UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INSULIN PRICING LITIGATION	**Case 2:23-md-03080 (BRM) (LDW)** **MDL No. 3080** JUDGE BRIAN R. MARTINOTTI JUDGE LEDA D. WETTRE

THIS DOCUMENT RELATES TO: 25-cv-01845

CERTIFICATION OF ELIZABETH PAIGE BOGGS SUPPORTING THE GOVERNMENT OF PUERTO RICO'S REPLY IN SUPPORT OF MOTION FOR LEAVE TO AMEND COMPLAINT

ELIZABETH PAIGE BOGGS, of full age, certifies and states:

1. I am an attorney at Motley Rice LLC admitted *pro hac vice* to practice in the District of New Jersey. I submit this certification supporting the Government of Puerto Rico's Reply in Support of Motion for Leave to Amend Complaint. As such, I am fully familiar with the facts set forth herein.

2. Attached as **Exhibit 1** to the Government of Puerto Rico's Reply in Support of Motion for Leave to Amend Complaint is a true and correct copy of the administrative complaint the Federal Trade Commission filed against Caremark RX, LLC, Zinc Health Services, LLC, Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., Ascent Health Services LLC, OptumRx, Inc., OptumRx Holdings, LLC, and Emisar Pharma Services LLC on November 26, 2024.

I certify under the penalty of perjury, pursuant to 28 U.S.C. § 1746(2), that the foregoing is true and correct.

DATED: July 14, 2025

/s/ *Elizabeth Paige Boggs*
ELIZABETH PAIGE BOGGS

Counsel for Plaintiff the Government of Puerto Rico

EXHIBIT 1

PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Lina M. Khan, Chair**
Rebecca Kelly Slaughter
Alvaro M. Bedoya
Melissa Holyoak
Andrew Ferguson

In the Matter of **Caremark Rx, LLC;** **Zinc Health Services, LLC;** **Express Scripts, Inc.;** **Evernorth Health, Inc.;** **Medco Health Services, Inc.;** **Ascent Health Services LLC;** **OptumRx, Inc.;** **OptumRx Holdings, LLC;** and **Emisar Pharma Services LLC.**	**Docket No. 9437**

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act ("FTC Act"), and by virtue of the authority vested in it by the FTC Act, the Federal Trade Commission ("Commission"), having reason to believe that Respondents Caremark, ESI, and Optum (collectively "PBM Respondents"); and Zinc, Ascent, and Emisar (collectively "GPO Respondents") have engaged in conduct that violates Section 5 of the FTC Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), stating its charges as follows:

PUBLIC

I. NATURE OF THE CASE

1. Americans pay too much for prescription drugs, including life-saving drugs like insulin. In fact, prescription drug prices in the U.S. are nearly three times higher than in other countries. In 2023, the U.S. spent over $722 billion on prescription drugs, nearly as much as the rest of the world combined. Many Americans struggle to afford the medications they need to survive.

2. This country's prescription drug affordability crisis is partly driven by Respondents' manipulation of drug price competition for their own gain. Normally, companies compete by lowering prices. And normally, insurance systems function by the healthy subsidizing the sick. Respondents' conduct has turned these basic principles on their head. This case challenges their role in designing, directing, and overseeing a drug reimbursement system, which generates billions of dollars in rebates and fees for them while incentivizing drug manufacturers to *raise* (not lower) the sticker price (i.e., list price) of their drugs. As a result, many diabetics and other sick patients are stuck paying significantly more for life-saving medications like insulin.

3. Pharmacy benefit managers (PBMs) act as middlemen, overseeing prescription drug coverage and reimbursement for health plans, health plan sponsors, and more than 200 million Americans. Through dozens of mergers, the PBMs have horizontally concentrated and vertically integrated. Three dominant pharmacy benefit managers—Caremark, ESI, and Optum—administer approximately 80% of all prescriptions in the United States.

4. Positioned at the center of the intricate and opaque pharmaceutical distribution chain, the PBM Respondents wield significant influence over which drugs patients can access, and at what price. The PBM Respondents create drug formularies, which are lists of preferred and non-preferred drugs grouped by categories. Their clients—including companies and organizations that sponsor commercial health plans—use these formularies to steer insured patients to certain prescription drugs and away from others.

5. About a decade ago, the PBM Respondents introduced restrictive formularies that completely exclude certain drugs from coverage. The introduction of these restrictive or exclusionary formularies was a game changer. Manufacturers now faced the significant risk that their products would be excluded outright from insurance coverage for tens of millions of patients. Leveraging this threat of exclusion, Respondents began demanding higher and higher rebates from drug manufacturers in exchange for placing those drugs on their restrictive formularies. In a single year, one PBM Respondent collected more than $[redacted] billion in rebates and an additional $[redacted] billion in associated fees.

6. The race for higher rebates, in principle, should have reduced drug costs for patients. For many patients, however, the reality is quite different. To satisfy the PBM Respondents' insatiable demand for larger rebates—and to preserve the manufacturers' own profits—manufacturers have steadily increased the list price of their drugs, leading to artificially inflated list prices that are disconnected from the actual cost of the drugs to insurers. Yet, many patients' out-of-pocket expenses are directly or indirectly tied to these inflated prices. For example, uninsured patients may pay the full list price, while insured patients with high

deductibles or co-insurance face costs based on these inflated list prices. As a result, as rebates and list prices rise in tandem, these groups of patients are burdened with higher out-of-pocket costs for their medications.

7. The harm caused by this broken system is far-reaching. Respondents have created an opaque drug pricing and reimbursement system, which benefits them, but which deliberately obscures the full scope of harm and financial cost from insurers and patients who may be unknowingly shouldering the burden of inflated list prices.

8. Insulin is the poster child of Respondents' broken drug pricing system. Diabetes is among the most widespread diseases in the United States, afflicting an estimated 38.4 million Americans. In 2021, diabetes was the eighth leading cause of death in the United States. And the prevalence of diabetes continues to rise. In 2023, the Centers for Disease Control and Prevention (CDC) calculated that the number of adults diagnosed with diabetes has more than doubled in the past two decades. There is no cure for diabetes, but it can be managed. For many, the only way to manage the disease is with insulin injections. Insulin was first used as medication over a century ago, and today over 8 million Americans depend on insulin for their survival.

9. For nearly 85 years, insulin medications were affordable. For example, in 1999, the average list price of Humalog, a widely used insulin, was only $21. Starting around 2012, however, the PBM Respondents began demanding increasingly higher rebates and fees from insulin manufacturers in exchange for exclusive placement on their formularies. This chase-the-rebate strategy proved highly effective (and profitable) for the PBM Respondents. Manufacturers paid rebates as steep as [redacted]% off the list price to secure exclusive formulary coverage. But this approach had a profound consequence: as the Respondents demanded more rebates, insulin manufacturers sharply inflated the list prices of their products. By 2017, Humalog's price had soared to more than $274—a staggering increase of more than 1,200%. In the past ten years alone, spending on insulin in the United States has tripled—from $8 billion in 2012 to $22.3 billion in 2022.

10. The rising list price of insulin has led to severe harm. By 2019, the PBM Respondents estimated that one out of every four insulin patients could not afford their medication. More than a million patients reported rationing their insulin, a dangerous practice that can lead to devastating health complications, including death.

11. Worse, Respondents' tactics have effects beyond insulin. The Respondents' demand for larger rebates has also inflated list prices for other critical drugs including treatments for autoimmune diseases and inflammatory conditions. Patients whose out-of-pocket costs are tied to these inflated list prices may spend hundreds of dollars per prescription. In some cases, the patient may pay more at the pharmacy counter than the actual cost to their commercial insurer. In other words, the insurer functionally makes a profit from the prescription, instead of paying its share of the cost. This turns the normal insurance model on its head with the sick subsidizing the healthy, rather than the other way around. As one PBM manager bluntly put it: "I don't see how it's justifiable to charge someone 100% of the cost of the drug (during the deductible [phase]), while you receive a rebate on the backend … I can't think of any other insurance industry that works like that[.]"

12. It is time to put an end to the Respondents' unfair and unlawful business practices and to prevent their recurrence.

II. JURISDICTION

13. Respondents are, and at all relevant times have been, corporations, as the term "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

14. Respondents' general business practices and the unfair methods of competition and unfair acts or practices alleged here are "in or affecting commerce" within the meaning of Sections 4 and 5 of the FTC Act, 15 U.S.C. §§ 44, 45.

III. RESPONDENTS

A. Caremark/Zinc Respondents

15. Respondent Caremark Rx, LLC ("Caremark") is a Delaware limited liability company with its principal place of business at One CVS Drive, Woonsocket, Rhode Island. Caremark Rx, LLC is a wholly owned indirect subsidiary of CVS Health Corporation.

16. Caremark is engaged in the business of providing pharmacy benefit services and is the largest PBM in the United States. In 2023, Caremark administered 2.3 billion—or approximately 34%—of total prescription claims in the United States. In 2022, Caremark recorded $169.2 billion in revenue.

17. Respondent Zinc Health Services, LLC ("Zinc") is a Delaware limited liability company with its principal place of business at One CVS Drive, Woonsocket, Rhode Island. In 2020, CVS Health Corporation established Zinc as a group purchasing organization for Caremark's PBM business. CVS Health Corporation co-owns Zinc and appoints three out of the four members of Zinc's Board of Directors. Zinc negotiates rebates with drug manufacturers on behalf of Caremark's and other third parties' commercial clients.

B. Express Scripts/Ascent Respondents

18. Respondent Express Scripts, Inc. is a Delaware company with its principal place of business at One Express Way, St. Louis, Missouri. Express Scripts, Inc. is engaged in the business of providing pharmacy benefit services and is the second largest PBM in the United States. In 2023, Express Scripts, Inc. administered approximately 23% of total prescriptions in the U.S. Express Scripts, Inc. is a wholly owned direct subsidiary of Evernorth Health, Inc. and a wholly owned indirect subsidiary of Cigna Corporation.

19. Respondent Evernorth Health, Inc. ("Evernorth") is a Delaware company with its principal place of business located at One Express Way, St. Louis, Missouri. In 2022, Evernorth earned $140.3 billion in revenue, the majority of which came from ESI. Evernorth is a wholly owned direct subsidiary of Cigna Corporation. Evernorth is involved in Express Scripts, Inc.'s provision of PBM services.

20. Respondent Medco Health Services, Inc. ("Medco") is a Delaware corporation with its principal place of business at 100 Parsons Pond Drive, Franklin Lakes, New Jersey. Medco is a wholly owned indirect subsidiary of Cigna Corporation. Medco supports Cigna's PBM functions.

21. Express Scripts, Inc., Medco Health Services, Inc., and Evernorth Health, Inc. are referred to collectively as "ESI" or "ESI Respondents."

22. Ascent Health Services LLC ("Ascent") is a Delaware limited liability company with its principal place of business at Mühlentalstrasse 36, 8200 Schaffhausen, Switzerland. In 2019, ESI established Ascent as a group purchasing organization for ESI's PBM business. ESI co-owns Ascent and appoints three out of the five members of Ascent's Board of Directors. Ascent negotiates rebates with drug manufacturers on behalf of ESI's and other third parties' commercial clients.

C. Optum/Emisar Respondents

23. Respondent OptumRx, Inc. is a California corporation with its principal place of business at 11000 Optum Circle, Eden Prairie, Minnesota. OptumRx, Inc. is a wholly owned indirect subsidiary of UnitedHealth Group Inc. OptumRx, Inc. is responsible for supporting all PBM services provided by UnitedHealth Group Inc.

24. Respondent OptumRx Holdings, LLC is a Delaware corporation with its principal place of business located at 11000 Optum Circle, Eden Prairie, Minnesota. OptumRx Holdings, LLC is a wholly owned indirect subsidiary of UnitedHealth Group Inc. and the direct parent company of OptumRx, Inc.

25. OptumRx, Inc. and OptumRx Holdings, LLC are collectively referred to as "Optum" or "Optum Respondents."

26. Optum is engaged in the business of providing pharmacy benefit services and is the third largest PBM in the United States. In 2023, Optum administered approximately 22% of total prescription in the U.S. In 2022, OptumRx recorded $99.8 billion in revenue.

27. Respondent Emisar Pharma Services LLC ("Emisar") is a Delaware limited liability company with its principal place of business in Ireland. In 2021, Optum established Emisar as a group purchasing organization for Optum's PBM business. Emisar is a wholly owned indirect subsidiary of UnitedHealth Group Inc. Emisar negotiates rebates with drug manufacturers on behalf of Optum's commercial clients.

IV. BACKGROUND

A. PBMs are central actors in pharmaceutical transactions, influencing drug pricing, rebates, and sales

28. PBMs administer pharmacy benefit management services on behalf of clients. These clients are also generally known as payers, and include employers, health insurer plans, labor unions, employer coalitions, and government entities. PBMs provide various services to

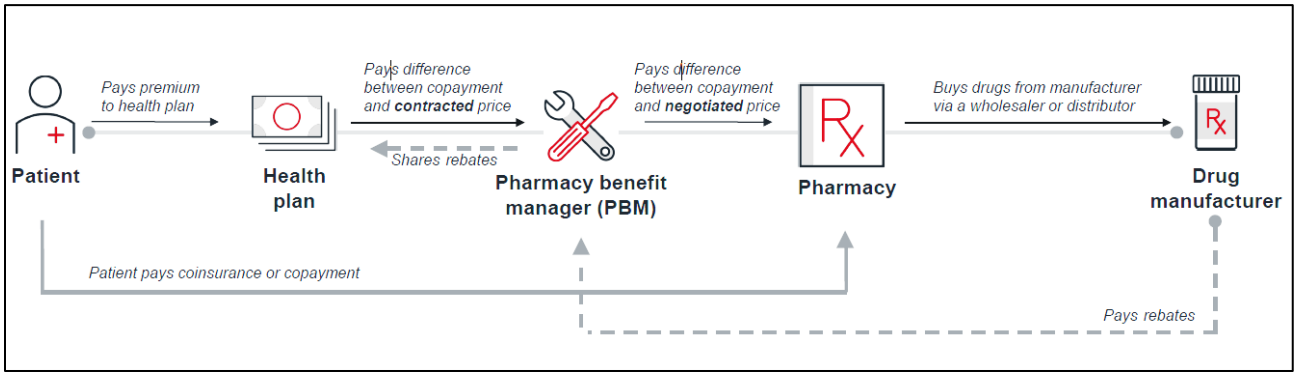
these payers including developing drug formularies, creating and managing networks of pharmacies, processing prescription drug claims, reporting drug expenditures, creating and administering clinical programs, and negotiating with pharmaceutical manufacturers for rebates on behalf of their clients.

29. PBMs began by providing claims processing and administrative services for health insurance companies in the late 1960s. Over time, however, their services expanded and PBMs began acting as intermediaries between the various segments of the pharmaceutical supply chain. Over the last 20 years, PBMs have also become increasingly concentrated. Caremark, ESI, and Optum have all gained share in the provision of PBM services through mergers and acquisitions. For example, ESI acquired Medco Health Solutions in 2012—combining the then first and third largest PBMs; Optum acquired Catamaran in 2015—combining the then third and fourth largest PBMs; and Caremark merged with Aetna (which had its own PBM) in 2018—increasing the share of the largest PBM in the U.S. today.

30. These PBMs have also become vertically integrated within large conglomerates that provide a broad range of services across the health care sector. The PBMs are integrated with private drug labelers, pharmacies, health care providers, GPOs, and insurance companies. This vertical integration has allowed the PBMs and their affiliates to leverage their power along every link in the pharmaceutical supply chain.

31. These behemoth PBMs came to exert enormous influence over drug pricing and purchasing decisions. When a patient fills a prescription at a retail pharmacy, the patient's out-of-pocket cost for the drug can vary depending on several financial arrangements within the pharmaceutical chain. Today, PBMs are at the center of these financial arrangements, contracting with drug manufacturers, health plan sponsors, and pharmacies.

Payment flow between stakeholders for pharmacy benefit drugs:



Formulary Development

32. One of the key ways PBMs exert influence over drug pricing and purchasing decisions is by creating drug formularies. A drug formulary is a list of prescription drugs covered by a health plan. Formularies often separate drugs into multiple tiers, and drugs on "preferred" tiers are typically cheaper for patients. For example, a common formulary design has three tiers: tier 1 includes mostly generic drugs and has the lowest patient out-of-pocket cost; tier 2 includes

preferred branded drugs with a higher out-of-pocket cost; and tier 3 includes non-preferred branded drugs with the highest patient out-of-pocket cost. This formulary design drives prescriptions toward the lowest tiers, including generic or preferred branded drugs.

33. Some drug formularies are more "open," meaning the formulary covers all or nearly all medications. Other formularies are relatively "closed," meaning the formulary includes only certain drugs, and excludes others, used to treat a specific condition. Generally, a health plan will not reimburse any part of the cost for an excluded drug. It follows that a physician is more likely to prescribe a drug that is covered on their patient's health plan formulary. Thus, a drug's formulary coverage dramatically impacts the drug's cost and utilization.

34. The PBM Respondents all offer several standard commercial formularies with different drug exclusion levels, ranging from open to more closed. The most-utilized commercial formularies all have a significant number of drug exclusions.

35. As of 2021, Caremark's flagship Standard Control Formulary, which excludes drugs, covered more than [redacted] million people. Caremark's more open Basic Control Formulary covered approximately [redacted] million people.

36. As of 2023, ESI's flagship National Preferred Formulary, which excludes drugs, covered approximately [redacted] million people. ESI's more open Basic Formulary covered approximately [redacted] million people.

37. As of 2023, Optum's flagship Premium Formulary, which excludes drugs, covered more than [redacted] million people. Optum's more open Select Formulary covered approximately [redacted] million people.

38. Because formularies serve a crucial role in determining patient access to prescription drugs, PBMs' central role in formulary design gives them significant leverage to extract price concessions from drug manufacturers. If a PBM excludes a drug from its formulary, the manufacturer risks losing a significant portion of sales among patients covered by that formulary. Conversely, if a PBM "preferences" or "prefers" a drug by placing it on a more favorable tier compared to competing products, it can boost the drug's sales volume and market share.

Rebate Negotiation

39. PBMs also exert influence over drug pricing and purchasing decisions by conditioning preferential treatment on their drug formularies on manufacturer rebates.

40. Drug manufacturers pay rebates that are based on a percentage of the wholesale acquisition cost (WAC) of their product. Drug manufacturers set the WAC, which is often referred to as the drug's "list price."

41. The list price of a drug minus any rebates and fees paid by the manufacturer is referred to hereinafter as the drug's "net price."

42. In recent years, each PBM Respondent has created a group purchasing organization (GPO) to negotiate commercial rebates with drug manufacturers on behalf of the PBMs. These GPOs (Respondents Zinc, Ascent, and Emisar) now perform the same commercial contracting function that the PBMs previously handled directly. In fact, many of the personnel at the GPO Respondents who negotiate or oversee commercial rebate contracts with drug manufacturers previously held the same role for the PBM Respondents. The PBM Respondents simply moved their commercial rebate contracting functions to the GPO Respondents' corporate structure. Now, the GPO Respondents enter into commercial rebate contracts with drug manufacturers, and the PBM Respondents utilize these rebate rates for their commercial clients.

43. PBM Respondents, now through GPO Respondents, solicit commercial bids from manufacturers using rebate grids. Manufacturers submit commercial bids by filling out these grids with different rebate rates for different levels of exclusivity: exclusive coverage (1 of 1 manufacturer), dual coverage with another manufacturer (1 of 2), and multiple manufacturers (1 of many).

44. Generally, manufacturers are willing to pay higher rebates for more preferential treatment of their drugs on formularies. For example, in 2022, one insulin manufacturer, Sanofi-Aventis U.S., paid Optum base rebates of [redacted]% of WAC for its insulin drug Lantus where Sanofi was the only long-acting insulin manufacturer on the formulary. In contrast, Sanofi paid Optum base rebates of only [redacted]% of WAC for Lantus where Sanofi was one of many long-acting insulin manufacturers on the formulary.

45. PBM Respondents, now through GPO Respondents, extract administrative fees from drug manufacturers as part of commercial rebate negotiations. PBMs attribute administrative fees to maintaining and overseeing the rebate program, negotiating and contracting with clients to participate in the rebate program, monitoring compliance with rebate eligibility requirements, and calculating and invoicing the rebates applicable to eligible drug utilization.

46. Administrative fees are typically calculated as a percentage of a drug's WAC, ranging from [redacted]% to [redacted]%. For example, a 2022 rebate agreement between Emisar (Optum's GPO) and Eli Lilly, another insulin manufacturer, had an administrative fee of [redacted]% of WAC. Because administrative fees are typically calculated as a percentage of WAC, the PBMs and GPOs collect higher fees on a drug with a higher WAC than a drug with a lower WAC even though the PBMs and GPOs provide the same services.

47. PBM Respondents, now through GPO Respondents, also extract data fees from manufacturers as part of their commercial rebate negotiations. Nominally, a data fee grants manufacturers access to a portal that contains utilization and other data for the manufacturer's drugs.

48. Data fees, sometimes referred to as [redacted] fees or [redacted] fees, are typically calculated as a percentage of a drug's WAC, ranging from [redacted]% to [redacted]%. For example, a 2022 rebate agreement between [redacted] GPO) and [redacted] had a data fee of [redacted]% of WAC. Because data fees are calculated as a percentage of WAC, the PBMs and

GPOs collect higher fees on a drug with a higher WAC than on a drug with a lower WAC, even though the PBMs and GPOs provide the same data services.

49. PBM Respondents, now through GPO Respondents, may also extract WAC-based fees from manufacturers in exchange [redacted]. For example, a 2022 rebate agreement between [redacted] GPO) and Lilly had an [redacted] of [redacted] % of WAC depending on [redacted]. And a 2022 rebate agreement between [redacted] and Sanofi had a [redacted] of [redacted] % for a particular drug [redacted]. Because these fees are typically calculated as a percentage of WAC, the PBMs and GPOs collect higher fees with a higher WAC drug than a drug with a lower WAC even though the PBMs and GPOs provide the same services.

50. PBMs implement drug formularies for their payer clients. PBMs develop standard commercial formularies, including their flagship formularies identified in paragraphs 35-37, that clients can adopt "off the shelf." Each of the three PBM Respondents, often for an extra fee, also allows clients to customize their own drug formularies. Custom formularies can range from a client making a few deviations to a standard PBM formulary to a fully customized formulary tailored to a client's specific needs. Many employers and commercial health plan sponsors lack the resources or pharmaceutical expertise necessary to develop their own formularies, so they outsource drug formulary decisions entirely to PBMs and accept the standard formularies that PBMs offer.

51. PBMs also handle the flow of rebate payments from drug manufacturers to the commercial payers. PBMs claim they pass on the vast majority of the drug rebates to their payer clients, though almost never directly to the patients.

52. In their May 2023 Congressional testimony, the PBM Respondents asserted that they pass on approximately 95% to 98% of the rebates they receive from drug manufacturers on behalf of the PBMs' clients. Industry reporting and data, however, suggest that these claims may be exaggerated, with PBMs actually retaining a larger portion of rebates and fees. According to the data that PBMs reported to the Texas Department of Insurance, fifteen PBMs collected a total of $4.39 billion in rebates, fees, and other payments from drug manufacturers in 2022 on health plans issued under Texas law. Of this, the PBMs kept $409 million—9.32%—for themselves.

53. A 2022 Drug Channels analysis of the Texas Department of Insurance data found that the data from 2016 to 2021 "tell a compelling and fairly consistent tale about what happened to the manufacturers' payments to PBMs." The Drug Channels analysis concluded that between 2016 and 2021, the PBMs retained between 7% and 21% of manufacturers' total payments, totaling hundreds of millions of dollars.

54. Payers' limited visibility into specific rebates and fees makes it difficult to verify pass-through. The formation of the GPO Respondents further exacerbated payers' ability to determine whether rebates and fees are actually being passed through, because the Respondents

do not disclose the amount of fees retained by the GPOs. Moreover, the GPO Respondents often make their rebate contracts with manufacturers available for payers' review only on-site at the GPOs' physical locations—outside the United States for two of the GPO Respondents—further obscuring payers' visibility into pass-through. A former Optum executive who helped set up Emisar, Optum's GPO, candidly explained, "The intention of the G.P.O. is to create a fee structure that can be retained and not passed on to a client."

55. Rebates that are passed on to the health plan may reduce the plan's (but not necessarily the patient's) overall net cost of a drug. Hereinafter, "net cost" refers to the actual cost to the payer, after factoring in the rebates and fees that are passed on to the payer. Payers then choose whether to retain the rebates or apply them at the point of sale (i.e., the pharmacy counter) when the patient purchases the drug that earns the rebate. According to the Texas Department of Insurance data, only 0.0002% of the collected rebates were shared directly with the patients who took the drugs.

B. Certain patients' out-of-pocket costs are tied to a drug's list price

56. Different patients may pay vastly different amounts for the very same drug. Patient cost depends on several factors, including whether the individual has health insurance, and if so, the drug benefits provided by that insurance.

57. Uninsured or cash-paying patients may pay for the prescription based on a drug's full list price.[1] Because these patients are not covered by health insurance, they do not receive rebates or other price concessions that a PBM negotiates with the manufacturer. According to the CDC National Center for Health Statistics, 8.4% or 27.6 million Americans did not have health insurance in 2022.

58. Most Americans have health insurance. But even among insured Americans, out-of-pocket costs greatly vary for the same drug. A patient's health insurance may be either commercial or government-sponsored (e.g., Medicare, Medicaid). Most Americans with commercial health insurance get coverage through their employer. According to U.S. Census Bureau data, over 183 million individuals were enrolled in employer-sponsored commercial insurance in 2019, compared to 33 million individuals with direct-purchase commercial plans and 58 million individuals enrolled in Medicare, the next largest category.

59. Employers providing health insurance may be self-insured or fully insured. Self-insured employers assume the financial risk of providing health benefits to employees. Fully insured employers, on the other hand, outsource the financial risk to the health insurance company. In 2023, approximately 65% of employees were enrolled in self-insured employer plans. PBMs administer pharmacy benefits for both self-insured and fully insured clients.

[1] The price at the pharmacy counter that is used as the basis for calculating a patient's out-of-pocket cost is generally either the drug's usual and customary price (U&C) or a discounted Average Wholesale Price (AWP), rather than WAC. However, both U&C and discounted AWP are closely correlated to and often approximate WAC for branded drugs. For simplicity, we refer to WAC and other prices based on WAC as the "list price."

60. How much an insured patient pays for a prescription is determined by the drug benefit in the patient's health plan. A patient's cost for their drug benefits includes two key components: monthly premiums and out-of-pocket expenses. A monthly insurance premium is a fixed amount the patient must pay regardless of their drug purchases. Out-of-pocket expenses are the costs the patient incurs when buying a prescription drug. Depending on the benefit design, the out-of-pocket expense may be structured as a copayment (a flat amount, e.g., $25 per drug), a coinsurance (a percentage of the total drug cost at the pharmacy, e.g., 30% of the cost), or a deductible (an amount the patient must pay before the plan begins contributing to the drug cost, e.g., $2,000).

61. When an insured patient buys a prescription drug at a pharmacy, the pharmacy charges the patient the out-of-pocket cost determined by the patient's benefit design. The pharmacy then receives reimbursement for the remainder of the drug's cost. Using a simplified example, if a drug costs $100 at the pharmacy, a patient with a $25 copay would pay $25, with the health plan (through the PBM) paying the pharmacy the remaining $75. A patient with 30% coinsurance would pay $30, with the payer covering $70, while a patient in the deductible phase of their health insurance plan would pay the full $100.

62. Patients with a copay—since they are responsible for a predetermined fixed amount—are mostly indifferent to the drug's actual list price. However, patients with coinsurance or those in the deductible phase typically have their out-of-pocket costs calculated based on the drug's list price before any rebates are applied. As a result, these patients may end up paying more out-of-pocket for drugs with higher list prices, even if the PBM and payer receive significant rebates.

63. According to KFF's (f/k/a Kaiser Family Foundation) 2023 Employer Health Benefits annual survey, at least 23% of workers with employer-based drug coverage pay coinsurance for second-tier drugs—generally, preferred branded drugs. The average coinsurance for second-tier drugs, or preferred brands, in 2023 was 26%.

64. With health insurance premiums rising far faster than inflation in recent years, patients have increasingly enrolled in high deductible health plans (HDHPs) that require them to meet a high deductible in exchange for somewhat more affordable monthly premiums. Per Internal Revenue Service guidelines, HDHPs have deductibles between $1,600 and $8,050 for self-only coverage and between $3,200 and $16,100 for family coverage in 2024. According to KFF's 2023 Employer Health Benefits annual survey, 29% of adults with employer-based health insurance were enrolled in a HDHP, up from 19% in 2012.

65. Lower-income patients are more likely to enroll in HDHPs without accompanying tax-advantaged health savings accounts. A 2017 National Health Interview Survey by the CDC found that adults in the survey's lowest income category (where income levels ranged from below the federal poverty line up to 138% of the federal poverty line) were the most likely of the income categories to have HDHPs without health savings accounts.

66. Health plans can mitigate some of their patients' exposure to high drug list prices by applying drug rebates directly at the pharmacy counter when the patient purchases the drug that earns the rebate, commonly known as a point-of-sale rebate. When all rebates from

manufacturers are applied to a drug at the point of sale, a patient's coinsurance or deductible payment for the drug is lower because it is effectively based on a measure closer to net price, rather than the list price.

67. In most cases, however, payers opt not to implement point-of-sale rebates. According to the 2023 Milliman Medical Index industry report, point-of-sale rebates are rare. Consequently, deductibles and coinsurance may shift a larger portion of the drug cost from the health plan to the patient, particularly when the manufacturer pays substantial rebates on a drug.

68. Indeed, for drugs with large rebates, a patient with out-of-pocket costs pegged to the list price may find themselves paying more at the pharmacy counter than the drug's actual net cost to the commercial payer. When a patient's out-of-pocket cost is tied to the list price, and the rebate is not passed on to the patient, the payer's "cost share" for the drug may be negative—that is, the commercial payer may functionally make money when a patient fills that prescription.

69. A simplified example illustrates this dynamic, involving a drug with a $100 list price, and a 75% rebate:

List price	$100
Rebate Rate	75%
Rebate Amount	$75
Rebated Price (net cost to the payer)	**$25**
Coinsurance Rate	30%
Coinsurance Amount (what the patient pays)	**$30**

70. In this example, despite being responsible for 30% coinsurance, the patient pays more for the drug ($30) than the rebated price ($25). Meanwhile, the commercial payer pays the pharmacy (through the PBM) the remaining $70 for the drug ($100 minus $30 coinsurance), but may ultimately receive $75 in rebates from the manufacturer (through the PBM), resulting in a $5 net gain from the prescription. With a $100 or more deductible, the cost burden may be even more pronounced, as the patient may bear the full $100 expense, while the commercial payer pays nothing and receives a rebate.

71. An insured patient's drug benefit design determines the patient's out-of-pocket cost for the drug at the pharmacy counter. The drug benefit design is largely a combination of two key components: formulary tiering and the cost-sharing between the payer and the patient associated with the tiers.

72. PBMs play a critical role in both of these components. Commercial payers frequently outsource their drug coverage decisions entirely to PBMs; PBMs create the drug formularies and place the drugs on the various formulary tiers. PBMs also heavily influence cost-sharing associated with formulary tiers. For example, PBMs often require health plans to adopt minimum copay or coinsurance differentials between formulary tiers. PBMs also offer strategy and benefit design consulting services to payers and may model the financial implications of benefit design choices. For example, according to one contract, Caremark is obligated to meet

annually with the client to "review plan strategy" and to provide "plan design modeling" that shows "cost and member impact associated with potential plan design changes."

73. PBMs may also assist in creating and distributing plan documents that describe a health plan's pharmaceutical benefit cost-sharing obligations, including whether patients are responsible for a copay, a percentage coinsurance, or a deductible.

C. Insulin is a life-saving medication for millions of diabetics

74. Naturally occurring insulin is a hormone produced by the pancreas and released into the body to turn blood sugar (or glucose) into energy. Without insulin, glucose builds up in the bloodstream leading to high blood sugar (or hyperglycemia).

75. Diabetes is a chronic health condition that occurs when a person's body cannot produce enough insulin (type 1 diabetes) or cannot use insulin properly (type 2 diabetes). Untreated diabetes can cause serious health problems, such as heart disease, stroke, kidney disease, vision loss, nerve damage, life-threatening infection, and amputations. The CDC ranked diabetes as the eighth leading cause of death in the United States in 2021, with over 100,000 deaths in which diabetes was listed as the underlying cause.

76. Diabetes is one of the most prevalent diseases in the United States. The National Diabetes Statistics Report estimated that in 2021, 29.4 million people in the United States, or 8.9% of the U.S. population, had diagnosed diabetes. The prevalence of diabetes continues to rise. In 2023, the CDC calculated that the number of adults diagnosed with diabetes has more than doubled in the past two decades.

77. There is no cure for diabetes, but diabetics can manage their blood sugar in part by taking insulin medication. Insulin medication is a biologic injectable drug made from a living organism, designed to regulate the body's blood glucose levels. Insulin was first used as a medication in 1922. According to the American Diabetes Association, in 2022, 8.4 million diabetics in the United States relied on insulin drugs to survive. All patients with type 1 diabetes take insulin, because their bodies do not produce it.

78. Four companies manufacture insulin for sale in the United States: Eli Lilly and Company ("Lilly"), Novo Nordisk Inc. ("Novo"), Sanofi-Aventis U.S. LLC ("Sanofi"), and Viatris Inc. (f/k/a Mylan). Lilly, Novo, and Sanofi have been selling insulin medications for over a century. Viatris is a far newer entrant, launching its first insulin drug, Semglee, in 2020. In 2022, Viatris Inc. sold its insulin portfolio to Biocon. Viatris and Biocon will be referred to collectively as "Viatris."

79. Most insulin products are available in both vial and pen (pre-filled syringe) dosage forms. The CDC classifies insulin types based on how fast and how long the insulin works in the body. Rapid-acting and long-acting insulins are the two main insulin categories.

80. Rapid-acting insulins lower blood sugar in approximately 15 minutes and continue to lower blood sugar for about two to four hours. Rapid-acting insulins are usually taken right before a meal to regulate the spike in blood glucose that occurs after eating. Between

2017 and 2022, rapid-acting insulins accounted for approximately 38-42% of total insulin sales in the United States.

81. Lilly sells Humalog and Lyumjev in the rapid-acting insulin category, with insulin lispro as the active ingredient.

82. Novo sells Novolog and Fiasp in the rapid-acting insulin category, with insulin aspart as the active ingredient.

83. Sanofi sells Admelog and Apidra in the rapid-acting insulin category, with insulin lispro and insulin glulisine, respectively, as the active ingredients.

84. In April 2022, the approximate shares of rapid-acting insulin commercial sales broke down as follows: Humalog (including branded and unbranded) had a [redacted]% share; Novolog (including branded and unbranded) had a [redacted]% share; Fiasp had a [redacted]% share; Lyumjev had a less than [redacted]% share; and Admelog had less than [redacted]% share. Humalog and Novolog have had a combined share of over 90% of the rapid-acting insulin sales since 2010.

[redacted]

85. Long-acting insulins, also known as basal insulins, lower blood sugar in approximately two hours and continue to lower blood sugar for up to 24 hours. Long-acting insulins are used to steadily regulate the body's blood glucose between mealtimes and overnight. Between 2017 and 2022, long-acting insulins accounted for approximately 46-48% of total insulin sales in the United States.

86. Lilly sells Basaglar and Rezvoglar in the long-acting insulin category, with insulin glargine as the active ingredient.

87. Novo sells Levemir and Tresiba in the long-acting insulin category, with insulin determir and insulin degludec, respectively, as the active ingredients.

88. Sanofi sells Lantus and Toujeo in the long-acting insulin category, with insulin glargine as the active ingredient.

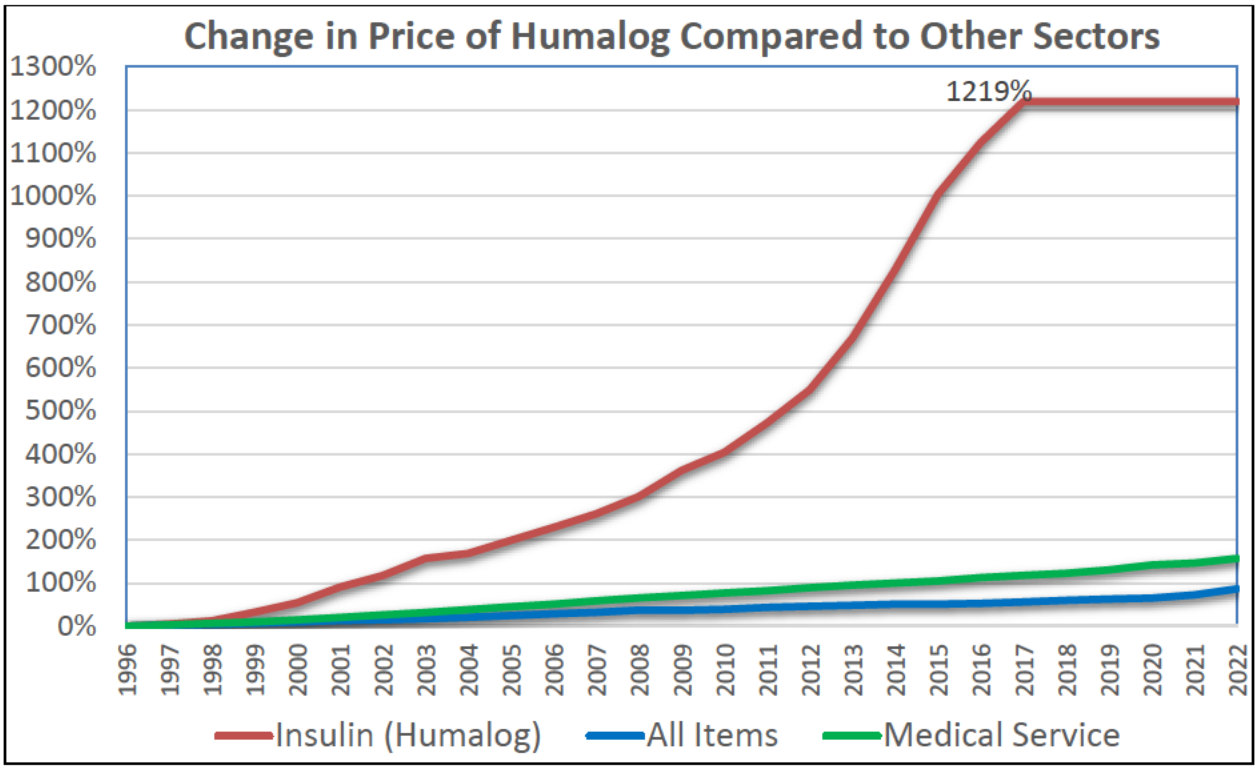
89. Viatris, and now Biocon, sells Semglee in the long-acting insulin category, with insulin glargine as the active ingredient.

90. In April 2022, the approximate shares of long-acting insulin commercial sales broke down as follows: Lantus had a [redacted]% share; Tresiba had a [redacted]% share; Basaglar had a [redacted]% share; Levemir had a [redacted]% share; Toujeo had a [redacted]% share; and Semglee had a [redacted]% share.

91. An insulin patient may take a combination of insulin drugs to regulate blood glucose levels throughout the day.

D. High list prices have made insulin drugs unaffordable for many patients

92. For nearly 85 years, insulin medication was affordable. For example, in 1999, the average list price of Humalog was $21. Over the past decade and a half, however, list price increases for insulin products have far outpaced inflation, even though the core drug has remained the same:



93. A 2022 report by the Department of Health and Human Services (HHS) found that the average list prices of insulin products nearly doubled between 2012 and 2016 alone. [redacted].

94. By comparison, between 2012 and 2018, the Consumer Price Index (CPI) rose only 9%, and the Prescription Drug CPI rose 20%.

95. These list price increases have resulted in particularly high out-of-pocket insulin costs for patients with commercial insurance and the uninsured. HHS found that in 2019, about 33% of patients using insulin had commercial health insurance. For commercially insured patients, 19% of monthly insulin prescriptions required out-of-pocket costs exceeding $70 per prescription. For uninsured patients, 27% of monthly insulin prescriptions involved costs greater than $70.

96. When patients cannot afford medication, they may be forced to ration their usage or abandon the therapy altogether. A peer-reviewed study published in the Annals of Internal Medicine found that 17% of total patients using insulin, and 18.8% of patients with commercial health insurance, reported rationing their insulin in 2021 because of its costs. Another peer-reviewed study in the Annals of Internal Medicine estimated that 1.3 million adults with diabetes in the United States rationed their use of insulin in 2021 by delaying refilling prescriptions, skipping doses, or taking smaller doses than needed. The study also found that rationing is more common among lower- and middle-income patients and among Black patients.

97. Abandoning or rationing insulin can lead to serious adverse health outcomes for patients, including death. An American Diabetes Association working group reported in 2020

that "people with high cost-sharing are less adherent to recommended dosing, which results in short- and long-term harm to their health."

98. One serious complication that can arise from rationing insulin is diabetic ketoacidosis, a condition where acids called ketones build up in the bloodstream and can cause a coma or even death. At an open meeting of the Commission in October 2021, the Commission heard directly from a mother who lost her 26-year-old son. After having difficulty affording his insulin, he tried to ration his insulin and died of diabetic ketoacidosis. The CDC reported that in 2020, 240,000 patients visited U.S. emergency rooms with diabetic ketoacidosis.

V. RESPONDENTS' UNLAWFUL CONDUCT

A. PBM Respondents developed exclusionary formularies, setting the stage for their chase-the-rebate strategy

99. Before 2012, drug formularies generally covered all approved medications. Rather than excluding clinically effective products, the PBM Respondents' formularies preferred certain products by placing them on different tiers, each with different patient out-of-pocket costs. While drug manufacturers sometimes offered modest rebates to secure a preferential tier placement, they generally did not have to worry about being completely excluded from the formulary and losing access to patients.

100. This dynamic changed around 2012 when the PBM Respondents sought ways to increase their leverage—and thus their profits—in negotiations with manufacturers. In part through a series of mergers and acquisitions, the PBM Respondents came to wield greater control over access to commercially insured patients. Accordingly, the PBM Respondents came to realize that they could extract more from manufacturers by threatening to exclude certain drugs from formularies.

101. Given that the PBM Respondents served as gatekeepers, manufacturers could not dismiss such threats lightly. If a manufacturer were excluded from a formulary that included a competitor in the same drug class, it would lose access to nearly all patients covered by that formulary, leading to significant sales losses. Consequently, the manufacturers became willing to offer higher rebates to secure preferential treatment. This shift gave rise to the exclusionary formulary.

102. The PBM Respondents began offering formularies that excluded clinically effective drugs from coverage. With these "closed" or exclusionary formularies, manufacturers faced the prospect of their product being entirely excluded. The PBM Respondents viewed these drug exclusions as "forever altering the landscape for how we negotiate with pharmaceutical manufacturers on our clients' behalf."

103. Recognizing it as a "bold move," Caremark became the first PBM to develop a commercial formulary with non-clinical drug exclusions. For example, in 2012, the predecessor to Caremark's Standard Control Formulary excluded all forms of Lilly's Humalog in favor of Novo's Novolog.

104. ESI initially thought that payers would resist Caremark's exclusion strategy as "clearly a play to obtain greater rebates[.]" A mere two years later, however, ESI introduced its own closed formulary. ESI's chief trade relations officer described the drug exclusion strategy as "a long-term game changer for rebate growth." An ESI Senior Account Executive characterized the new drug exclusions in its 2014 National Preferred Formulary—including Novolog, and Apidra—as "a great opportunity for us to increase rebates[.]"

105. In 2016, Optum introduced its own exclusionary drug formulary. As an Optum Project Manager explained to a plan's consultant, "[b]y excluding certain prescription drugs, we negotiate more aggressive discounts or higher rebates for drugs intended to treat the same condition."

106. Exclusionary formularies have expanded and now dominate the commercial space. The PBM Respondents pursue clients by guaranteeing a large portion of the rebate payments to the payers and push their standard formularies, which are based on guaranteed rebate amounts. As a result, commercial payers increasingly focus on maximizing rebates. The PBM Respondents recognize that their clients and clients' consultants "typically associate high rebate guarantees with value and do not always focus on lowest net cost[.]"

107. The PBM Respondents' most used commercial formularies all use drug exclusion strategies. Optum's Premium Formulary is "the most utilized of our standard formularies" and covers over [redacted] million people. Caremark's Standard Control Formulary covers more than [redacted] million people. ESI's National Preferred Formulary covers approximately [redacted] million people—[redacted] times as many as ESI's open Basic Formulary.

108. The PBM Respondents market these flagship formularies as providing "significant value for clients" by focusing on rebate maximization. For example, Optum presents its flagship Premium Formulary as having the "[m]ost rebates" (for payers). By comparison, Optum identifies its Select open formulary as providing the "[m]ost consumer choice" (for patients), and its Premium Value closed formulary as having the "[l]owest net spend" (for payers). Optum indicates that the Premium Value formulary, with 5-10% net spend savings over Premium, achieves this "lowest net cost" by "de-emphasizing rebates[.]"

109. Due to the presence of multiple competing manufacturers within each drug class, insulin products were a prime target for the PBM Respondents to extract rebate value from manufacturers in exchange for preferential formulary access.

110. Insulin products within the rapid-acting class are generally considered clinically substitutable. For example, in 2023, Caremark preferred Novo's rapid-acting insulins (Novolog and Fiasp) and excluded Lilly's rapid-acting insulins (Humalog and Lyumjev) from its flagship Standard Control Formulary. In the same year, ESI preferred Lilly's rapid-acting insulins (Humalog and Lyumjev) and excluded Novo's rapid-acting insulins (Novolog and Fiasp) from its flagship National Preferred Formulary.

111. Similarly, insulin products within the long-acting class are generally considered clinically interchangeable. For example, in 2023, Optum preferred Sanofi's long-acting insulins (Lantus and Toujeo) and excluded both Novo's long-acting insulins (Levemir and Tresiba) and

Lilly's long-acting insulin (Basaglar) from its flagship Premium Formulary. In the same year, though, Caremark and ESI both preferred Novo's Levemir and Tresiba and excluded Sanofi's Lantus from their flagship formularies.

B. Respondents demanded increasingly high rebates from manufacturers in exchange for favorable formulary placement

112. Insulin manufacturers need access to the PBM Respondents' formularies to effectively sell their insulin products. Novo estimated that, in 2021, [redacted]% of its entire insulin business was contracted through the PBM Respondents, with "the vast majority" of insured patients being "covered by those big three players." According to a Novo Senior Vice President responsible for strategic market access, securing coverage on the PBM Respondents' formularies was essential for reaching "large volumes of patients."

113. The PBM Respondents leveraged their size and the threat of excluding drugs from their formularies—resulting in significant sales losses—to demand higher rebates from insulin manufacturers. Indeed, when soliciting bids from manufacturers, the Respondents typically required manufacturers to maintain or increase the size of rebates or face outright rejection of the bid. Insulin manufacturers understood that "the magnitude of the rebate amount" was crucial and that they "had to compete for both net price and the amount of rebate in order to win access that PBMs prioritize." As a Novo Senior Vice President explained, "[t]he demands that PBMs have on insulin for rebates and discounts and fees have continued to increase over time." Lilly's then President of Diabetes echoed this sentiment, stating that rebates are "how you negotiate for formulary access."

114. The PBM Respondents were "[e]nacting narrow formularies so that the demands [for more insulin rebates] actually had some teeth." An internal Sanofi Market Access Background presentation highlighted that "US payers continue to use formulary placement to drive higher rebates." In just one year—from 2019 to 2020—Caremark and ESI excluded 109 and 54 more drugs, respectively. As Sanofi's Head of General Medicines Market Access explained, "the narrower the formulary, the greater that discount that can be extracted from the manufacturer."

115. To combat the "deep and real threat that [their] products would be removed from formularies at the largest PBMs," manufacturers dramatically increased the rebate rates on their insulin products.

116. In 2011, before the PBM Respondents introduced exclusionary formularies, Novo's contracted rebate rate to Caremark for Novolog was [redacted]%. In 2012, Caremark introduced the predecessor formulary to its flagship Standard Control Formulary, and preferred only Novo's insulins in the rapid-acting insulin class. In exchange for this exclusive formulary coverage, Novo [redacted] its rebate rate for Novolog to [redacted]%. By 2022, Caremark's Novolog rebate rate (negotiated by Zinc) for exclusive formulary coverage of its rapid-acting insulins had risen to [redacted]%.

117. In 2010, before the PBM Respondents introduced exclusionary formularies, ESI's contractual rebate rate for exclusive coverage of Humalog was [redacted]%. In 2014, ESI introduced

exclusions on its National Preferred Formulary, and preferred only Humalog in the rapid-acting insulin class. In exchange for this exclusionary formulary coverage, in 2015, Lilly more than [redacted] its offer for [redacted] commercial rebate rates, up to [redacted]%. By 2022, ESI's rebate rate (negotiated by Ascent) for exclusive coverage of [redacted] had risen to as high as [redacted].

118. In 2012, before the PBM Respondents introduced exclusionary formularies, Sanofi's average contractual rebate rate to Optum for Lantus was [redacted]%. In 2016, Optum introduced its Premium Formulary, and preferred only Sanofi insulins in the long-acting insulin class. In exchange for this exclusive formulary coverage, Sanofi agreed to a rebate rate of [redacted]% for Lantus. By 2022, Optum's rebate rates for Lantus had risen to as high as [redacted]%.

C. Insulin manufacturers continually raised insulin list prices to counteract increasingly higher rebate demands

119. Respondents' chase-the-rebate strategy led them to prioritize the magnitude of rebates received from drug manufacturers over lower list prices. To "offset some of the dramatic and rapid changes in the rebates" resulting from this strategy, insulin manufacturers dramatically increased list prices.

120. Lilly increased the list price for Humalog U-100 from $122.60 in 2012 to $274.70 in 2017, an increase of 124%.

121. Novo increased the list price for Novolog U-100 from $122.59 in 2012 to $289.36 in 2018, an increase of 136%.

122. Sanofi increased the list price for Lantus U-100 from $114.15 in 2012 to $283.56 in 2019, an increase of 148%.

123. Lilly's former President of Diabetes attributed these price hikes to Respondents' rebate demands, stating, "the reason you see these type[s] of price increases is as a way to compensate for the very high rebates that the company would offer."

124. By 2018, diabetes had become the top category of drug spending for traditional (non-specialty) prescription drugs, according to a Drug Channels Institute analysis. Similarly, ESI's 2017 Drug Trend Report indicated that "diabetes medications were the most expensive among traditional therapies" and "the top diabetes drugs by spend continue to be insulins." In the third quarter of 2017, insulin was [redacted] per-member spend for Optum's commercial clients.

125. Generally, competition drives down prices as sellers try to win business. However, because the Respondents prioritized negotiating rebate amounts over net prices, manufacturers were able to *increase* list prices to offer larger rebates necessary to secure formulary access. Indeed, the insulin manufacturers often raised their list prices in lockstep, and many Americans found themselves paying drastically more money for the exact same drugs.

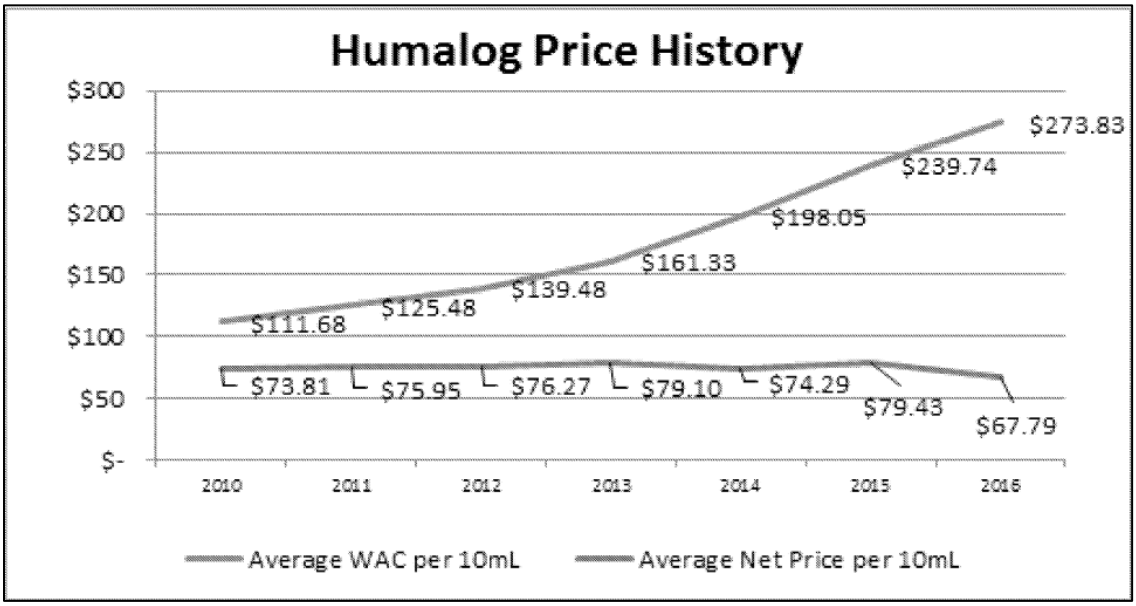
126. Lilly and Novo—the closest competitors in the rapid-acting class—specifically sought to maintain list price parity for Humalog and Novolog. Lilly's then President of Diabetes

explained that "we felt that we had to take similar price increases in order to be competitive … when Novo was taking price increases, if we didn't take similar price increases, we didn't think we could be competitive for [formulary] access."

127. Similarly, in the long-acting insulin class, Novo adjusted the list price of Levemir to match that of Sanofi's Lantus, which was its closest competitor in the long-acting insulin class.

128. Respondents' chase-the-rebate strategy meant that insulin manufacturers were not vying for favorable formulary access based on price, but instead based on higher rebates and fees paid to Respondents.

129. As list prices of insulin products continued to grow, they became wildly divergent from actual post-rebate net prices. In response to questions from Congress in 2017, Lilly charted the average list price and average net price of Humalog, revealing the growing disparity between the two.



130. Despite the growing rebates, the average net price of Humalog (after rebates and fees) continued to rise following the PBM Respondents' introduction of their exclusionary formularies—due to ever-escalating list prices. It took several years, around 2014-2015, for the net price of Humalog and other insulin products to begin to decline.

131. Although insulin net prices began to decline over time, patients whose out-of-pocket costs are tied to the artificially inflated insulin list prices continued to pay more. For example, Sanofi reported that from 2012 to 2022, "the net price in commercial and Medicare Part D plans of our most prescribed insulin, Lantus [] 100 units/mL, has fallen approximately 55%." Despite this, "average out-of-pocket costs for Lantus patients with commercial insurance and Medicare have risen approximately 45% over that same period." Sanofi highlighted that "high cost-sharing, particularly for highly rebated therapies such as insulin, creates a financial barrier for patients" to access treatments, noting that its ability to lower costs for patients was

limited because "PBMs and health plans ultimately decide what a patient pays at the pharmacy counter."

D. Rather than reduce the list prices of their insulin products and face pushback from the Respondents, manufacturers introduced identical low WAC alternatives

132. The skyrocketing insulin list prices drew significant criticism from the media, public, and Congress. Beginning in 2017, insulin manufacturers explored ways to reduce insulin list prices either by directly cutting the WAC of some of their existing insulins or by launching new, lower WAC unbranded versions of the same drugs.

133. Lilly, Novo, and Sanofi all recognized that providing patients access to insulin with lower list prices would help address affordability concerns, create "positive media attention for providing a solution," and maybe even "becom[e] a catalyst for changing the dynamics with payers."

134. Though the manufacturers considered reducing the list prices of their current insulin products, they knew that the PBM Respondents preferred to maintain competition for rebates and valued higher rebates over price cuts.

135. Novo was concerned that if it decreased the list prices of its insulin drugs, "[c]ompetitors may not follow[,] putting [Novo] at a disadvantage." Novo's Senior Vice President of Market Access explained, "[i]f we were to reduce the WAC price of our products and subsequently reduce the rebate value and administrative fee value that was being provided, we would expect, based on the conversations we had had, to receive push-back from the payers" and risk being excluded from PBM drug formularies in favor of high list price, highly rebated rivals.

136. This sentiment was shared by all three insulin manufacturers. In June 2018, Lilly executives individually met in person with representatives from each of the three PBM Respondents to present a proposal for a [redacted]% reduction in the list price of Humalog. This proposed reduction would keep the net price of Humalog the same but would reduce commercial and Medicare rebates for Humalog by an estimated $[redacted] over roughly three-and-a-half years. Unsurprisingly, Lilly received feedback that "the three PBMs were not interested in this proposal. It was that matter of fact." As Lilly's former President of Diabetes bluntly explained, if "you're cutting the rebates by [redacted] percent, we're not going to win that business." By cutting the Humalog list price, "you have … lower rebate pool, and lower admin fees, do you think that the PBM is going to choose you? … If we were to do this, we likely [redacted], so the Lilly [sales] number would be zero."

137. Caremark said something similar to Sanofi in 2019. Although Caremark professed to seek lower insulin prices for patients, it made clear that "they would be challenged" to include an insulin product on formulary if the product "had a much lower WAC with a smaller rebate." The following year, Sanofi evaluated the market prospects for a low WAC insulin product, finding a "loss of coverage with key rebate-driven customers is anticipated, as a lower WAC

price inhibits our ability to compete on rebates and increases competitors [sic] ability to create a financial upside for formulary change."

138. For the PBM Respondents, list price cuts would mean the potential loss of rebate and fee revenue. The PBMs generally guarantee rebate payments to their clients, which means that the PBMs commit to paying a fixed amount of rebate for every prescription. If list prices fell, the rebates on those prescriptions would also fall. The PBM Respondents would in turn receive less in rebates from manufacturers, but still owe their clients the same fixed amount of rebates per prescription, making it costly for the PBMs to fulfill their guarantee commitments.

139. Rather than cutting list prices on their existing insulin products and risking losing formulary access, Lilly, Novo, and Sanofi each launched new, unbranded low WAC products. These low WAC insulin versions were identical to the high WAC versions in all clinical respects. The only differences were that they did not include branding and were significantly lower list price.

140. In May 2019, Lilly launched a low WAC version of Humalog, priced 50% below the WAC of branded Humalog.

141. In January 2020, Novo launched a low WAC version of Novolog, priced 50% below the WAC of branded Novolog.

142. In June 2022, Sanofi launched a low WAC version of Lantus, priced 60% below the WAC of branded Lantus.

143. The insulin manufacturers continued to offer the high WAC, highly rebated versions while pricing their low WAC insulin at roughly "net price parity" with the branded versions. Essentially, although the low WAC version had a different list price, the smaller rebate it offered resulted in a net price roughly equivalent to that of its high WAC counterpart. Manufacturers adopted this pricing strategy "so that the payer would be neutral" or "indifferent" between the two versions.

E. Despite the entry of low WAC alternatives, PBM Respondents continued to prefer high price, highly rebated insulins on their flagship formularies

144. The PBM Respondents, however, were not indifferent between the high WAC and low WAC insulin versions. Instead, they methodically disfavored the low WAC insulin products on their flagship commercial formularies, preferring only the high WAC versions, with high rebates and fees.

145. In 2019, both ESI and Optum were exclusively preferring Lilly insulins in the rapid-acting insulin class on their flagship commercial formularies. In May of that year, Lilly launched low WAC Humalog. The "payer feedback [was] that this [launch] will have a negative financial impact on them" because the low WAC version would yield significantly lower rebates. Consistent with this feedback, in a monthly formulary consultant meeting, ESI explained to its client that it "will likely exclude [low WAC Humalog] on the [flagship National Preferred Formulary] due to rebate impact." In fact, both ESI and Optum kept high WAC Humalog as the

only preferred rapid-acting insulin on their flagship formularies, excluding low WAC Humalog entirely.

146. In 2020, Caremark was exclusively preferring Novo's rapid-acting insulin products (Novolog and Fiasp) on its flagship Standard Commercial Formulary. In January of that year, Novo launched low WAC Novolog. Despite this, Caremark kept high WAC Novolog and Fiasp as the only preferred rapid-acting insulins on its flagship formulary, excluding low WAC Novolog entirely.

147. In 2022, Optum was exclusively preferring Sanofi long-acting insulin products (Lantus and Toujeo) on its flagship Premium Formulary. In June of that year, Sanofi launched low WAC Lantus. Nonetheless, Optum kept high WAC Lantus and Toujeo as the only preferred long-acting insulins on its flagship formulary, excluding low WAC Lantus entirely.

148. Across the board, the PBM Respondents opted to exclude low WAC versions of insulin from their flagship formularies—even though including the low WAC versions would expand access to insulin for a swath of patients without impacting the rebate rates PBMs received for the high WAC versions. Instead, the contractual rebate rates the manufacturers offer depend on the number of manufacturers preferred on the formulary, not the number of individual insulin products. Thus, the PBM Respondents' contracts with manufacturers would allow them to include low WAC insulin versions while still receiving the same large rebate rates for the high WAC versions.

149. For example, in [redacted] 2019 rebate contract with [redacted] highest rebate rate on high WAC [redacted] for [redacted] flagship formulary was [redacted] %. This rebate rate was conditioned on [redacted] being the only preferred *manufacturer* in the [redacted] category on [redacted] flagship formulary, not on whether high WAC [redacted] was the only [redacted] *drug* in the rapid-acting drug category. In other words, under the contract, [redacted]

150. Co-preferring low WAC insulins on the formulary, however, would lead to more patients using the low WAC versions, resulting in "a huge loss in rebate $." For example, [redacted] estimated that it would lose millions in rebates and fees by co-preferring low WAC [redacted] on its flagship formulary. Indeed, the insulin manufacturers posited that the PBM Respondents were unwilling to cover the low WAC insulin products on their flagship commercial formularies due to concerns about a potential "loss of rebate stream."

151. The PBM Respondents' preference for large rebates also impeded new entry into the insulin space. In August 2020, Viatris introduced its long-acting product, Semglee. Initially, Viatris tried to market Semglee at a single discounted list price point, 65% below the list price of Lantus, the most-utilized long-acting insulin, and at least 50% below other long-acting insulins on the market. However, Viatris soon discovered that the PBM Respondents did not reward Semglee's significantly lower list price with preferred formulary placement. Instead, Semglee failed to secure formulary coverage on any of the PBM Respondents' flagship commercial

formularies precisely because its lower list price could not deliver "rebate dollars comparable to existing brands." Viatris attributed the lack of "commercial uptake" for original Semglee to the "inability to replace current Lantus rebate flow."

152. In July 2021, the Food and Drug Administration designated Semglee as interchangeable with Lantus, meaning that Semglee could be substituted for Lantus at the pharmacy without the doctor writing a new prescription. But Viatris still needed PBM formulary access to achieve sales. Having learned from the failed initial launch, Viatris introduced two versions of interchangeable Semglee: a high WAC version that could generate rebates necessary for commercial formulary coverage and a low WAC version that provided patient affordability in other, non-commercial drug channels (which did not prioritize rebate maximization).

153. Viatris introduced this high WAC version of Semglee [redacted], even though an internal model showed that [redacted], the low WAC version was [redacted] on a per unit basis. The model determined that low WAC Semglee is [redacted] to Viatris because it incurs [redacted] WAC-based fees paid into the pharmaceutical distribution chain compared to the high WAC version. According to the model, while the "payer net" (i.e., the cost to the payer) for both high WAC and low WAC Semglee was nearly identical, Viatris's net margin for low WAC Semglee pens was $[redacted], in contrast to [redacted] $[redacted] for high WAC Semglee.

154. Viatris's pivot to a high WAC Semglee yielded immediate results. In October 2021, ESI decided to include high WAC Semglee on its flagship National Preferred Formulary, while excluding low WAC Semglee. Notably, [redacted] had provided guidance to Viatris on the appropriate "rebate rate … from a competitive standpoint" but did not offer similar guidance on the appropriate "net price." ESI did not [redacted] on its flagship formulary.

155. Viatris's new entry into the insulin market had the potential to shake up market dynamics by injecting more competition, and lower prices, into the long-acting insulin space. As a Sanofi Vice President observed, however, ESI's decision to "embrac[e] the high WAC version of [Semglee]" was "a stabilizing event" that would preserve the "high WAC/high rebate market for the foreseeable future." The well-recognized sentiment that rebates drive PBM formulary decisions led one Optum employee to quip: "[A]s long as [Viatris is] keeping the lower WAC they should price Semglee at twice the price of Lantus with a huge rebate and sell it to PBMs as a product that can cover their rebate guarantees #million dollar ideas."

156. Though the high list price, highly rebated insulin versions were more lucrative for Respondents, the practical effect of the PBM Respondents' decisions to prefer the high WAC insulin, and exclude the lower list priced versions, from their flagship formularies was to deprive many patients who would have been able to better afford the low WAC insulins of that option.

157. In addition to designing standard formularies, the PBM Respondents also assisted clients with making the decision to exclude low WAC drugs from their custom formularies. For instance, one of [redacted] major custom clients, [redacted], was "very concerned about not covering" low WAC [redacted] and thought that "[f]rom a PR perspective [redacted] will likely be pushed into covering" the low WAC drug. [redacted]

prepared modeling for [redacted], demonstrating that adding low WAC [redacted] to the preferred tier could result in a loss of over $[redacted] in manufacturer rebates and administrative fees. [redacted] then "leverage[d] [redacted] talking points … to block [low WAC] [redacted]

158. Because of the PBM Respondents' systematic exclusion of low WAC insulins from their flagship commercial formularies, these products had limited uptake and "never achieved the same level of access as the branded [high WAC] version."

159. In 2022, low WAC Humalog accounted for approximately [redacted]% of total Humalog volume. Lilly estimated that "only one out of three insured patients has access to [low WAC Humalog] through their insurance."

160. Similarly, in 2022, low WAC Novolog accounted for approximately [redacted]% of total Novolog volume, and low WAC Semglee accounted for approximately [redacted]% of total Semglee volume. For low WAC Lantus, which launched in 2022, "coverage was low" and "[u]tilization was even lower."

161. The insulin manufacturers were "disappointed" with the low commercial uptake of the low WAC insulins. But as a Novo Vice President bluntly observed, "low wac/low rebate [insulins] don't stand a chance in this system."

162. Because of how the Respondents designed this system, many diabetics were left paying inflated prices for insulin.

F. Respondents financially benefit from artificially inflated list prices, rebates, and fees

163. The Respondents were focused on maximizing rebate value, not on lower list priced insulin products. Although the PBM Respondents understood that preferencing high WAC insulin products led to higher out-of-pocket costs for certain patients, the Respondents continued their chase-the-rebate strategy because it benefited them. In the words of a Novo Vice President, the Respondents, as well as commercial payers, have become "addicted to rebates."

164. The Respondents benefit from the higher rebates and fees associated with high list prices and high WAC insulin products in two primary ways: first, the PBM Respondents and GPO Respondents retain a portion of the rebates and fees; and second, the PBM Respondents use high rebate numbers to attract clients.

165. The PBM Respondents retain some of the rebates from drug manufacturers, collectively amounting to hundreds of millions of dollars per year from their commercial lines of business and billions of dollars per year in total. Additionally, the PBM Respondents and GPO Respondents retain a portion of the various WAC-based fees they charge drug manufacturers. For example, a Caremark March 2022 financial review of PBM rebates shows that Zinc retains [redacted] to [redacted]% of the combined WAC-based [redacted] fees it receives from manufacturers, amounting to nearly $[redacted] million in just one year. And some fees, such as [redacted] data fees, are retained entirely by the GPO Respondents and "are not passed back" at all.

166. As insulin list prices increased, so did the WAC-based fees that the Respondents collected for insulin products. But the Respondents did not provide drug manufacturers any additional services. As Ascent's President noted, [redacted] In other words, the Respondents extracted and pocketed hundreds of millions of dollars without providing any additional value.

167. Retention of rebates and fees from drug manufacturers is a significant "component of profitability" for the PBM Respondents and the GPO Respondents.

168. This is particularly true for insulin products, which have been among the highest rebated drugs for the Respondents. From 2017 to 2020, the long-acting insulin drug category generated the largest rebate value for [redacted]. In the third quarter of 2019, rapid-acting and long-acting insulins were the [redacted] by combined invoiced rebate dollars and administrative fees on ESI's flagship formulary. These rebates and administrative fees for insulin products totaled $[redacted] in just one quarter.

169. In 2020, rebates from insulin products comprised $[redacted] out of $[redacted]—or [redacted]%—of Optum's total commercial rebates. In 2020, Optum realized $[redacted] from insulin products. In 2021, an Optum Vice President of Industry Relations noted that [redacted], "We can still drink down the tasty Lantus rebates."

170. In addition to the higher rebates and fees Respondents retain, the PBM Respondents use the large rebates they receive from high price, highly rebated products to attract commercial payer clients. The PBM Respondents recognize that higher rebates "are [a] major point in retaining and winning clients."

171. The PBM Respondents' contract negotiations with commercial payers often focus on a guaranteed rebate amount. PBMs frequently compete for clients by trying to offer the highest minimum guaranteed rebate values. As ESI's Senior Vice President of Account Management for Commercial Accounts explained, the "minimum guarantee … is part of the RFP process based on the request of the client and the consultant. And in my experience it's used to compare across PBM[s]."

172. By offering a higher rebate guarantee, a PBM's bid is optically more attractive to a potential client. As Lilly's then President of Diabetes explained, PBMs use the rebate dollars they obtain from manufacturers "in their negotiations to get employers to choose their PBM services" and "the more … rebates they can get relative to their competitors, the more money they will have to go and win … employer's services." A [redacted] presentation on client pricing summarized: "Higher earned rebates better enable PBM to achieve rebate [guarantees] and attractive bid optics."

173. The PBM Respondents shaped competition for providing PBM services around guaranteed rebates. As a result, commercial payers prioritize the size of the rebate guarantee when selecting a PBM. [redacted]

[redacted] A [redacted] Director of [redacted] expressed concern that impacting [redacted] ability to meet rebate guarantees "will cause a lot of risk to [redacted] and could "decrease [redacted] ability to stay competitive in the market place."

174. Accordingly, commercial clients generally avoid formulary options that provide fewer rebates. Optum's Premium Value Formulary, which "de-emphasiz[es] rebates," had [redacted] clients as of 2023. ESI's Flex formulary, which "takes rebates out of the equation," covered fewer than [redacted] people in 2022.

175. Commercial payers often focus on rebate guarantees in part because the PBM Respondents typically refuse to share drug-level rebate and fee amounts or net cost information with the payers.

176. Consequently, many payers are unaware of the specific rebate amounts for individual drugs and are unable to calculate a rebated drug's true net cost. As the Department of Health and Human Services' Inspector General found, most health plans were unaware of all the contract terms that determine the rebates they receive from drug manufacturers. A [redacted] Vice President remarked in 2019 that there were "only a handful of clients that get drug level rebate reporting," and a [redacted] Director noted that those clients who did were "more sophisticated than most clients." Indeed, in April 2020, only [redacted] out of thousands of [redacted] commercial clients received specific drug-level rebate reports, which [redacted] conceded are offered to clients "as a last resort."

177. By offering rebate guarantees, the PBM Respondents lock themselves into having to generate enough rebates to meet their guaranteed minimum rebate amounts. If they are unable to meet these rebate guarantees, they might be required to cover the shortfall from their own funds. These pressures incentivize the PBM Respondents to favor high WAC insulin products on their flagship formularies, as they generate larger rebates.

178. The PBM Respondents recognized that switching to low WAC versions of insulin would result in "a major hit to overall rebates and drag on rebate [guarantees]." In evaluating the low WAC Humalog launch in 2019, [redacted] noted, "[i]nsulins earn rebates in excess of the guarantees they generate and thus a [low WAC] launch poses a risk to rebate guarantees." A [redacted] presentation from the following year, 2020, summed up the situation for the PBM Respondents: when a lower WAC product is introduced, the client [commercial payer] sees a "minimal difference in *net cost*" and members [patients] "could see a significant reduction in out of pocket costs." From the PBM's perspective, however, the "[r]eduction in rebates earned makes PBM underperform on client rebate guarantees, causing PBM to absorb losses," in other words, lose money.

179. In fact, in 2020, [redacted] was already "highly underwater" on its rebate guarantees to a large client. Even though the client was focused on lowest net cost and "[didn't] want to 'chase' rebates," [redacted] personnel decided to not bring up low WAC [redacted] with the client, because they were worried about "a drop in rebates" and "get[ting] in big trouble

if we brought the account further into the hole." [redacted] later noted in an internal presentation that this client was "[c]ritical in mitigating rebate guarantee exposure."

180. Optum conducted a financial analysis on the impact of the low WAC Humalog launch on its profit and loss statement. Optum found that if volume shifted from high WAC Humalog to low WAC Humalog, [redacted] Specifically, Optum identified a [redacted] rebate risk, with [redacted] representing a loss to Optum's profitability from retained rebates. The remaining [redacted] was [redacted], "because we're so [redacted] Humalog to [redacted]"

181. As a result, PBM Respondents largely neglected low WAC insulins in the commercial channels—even though these low WAC insulins could have meaningfully expanded drug access for diabetics. As the ESI executive who managed the company's relationship with Lilly candidly stated, "[w]e've just not discussed [low WAC Humalog] much [redacted]"

G. PBM Respondents deliberately cause the burden of inflated list prices to shift onto certain patients

182. The PBM Respondents claim to act in the best interests of patients. ESI's Vice President of Pharma Contracting and Strategy says he views his "role [a]s lowering the cost of drugs for patients and for our clients." Optum's former Market President of Health Plans described "patient affordability" as a "top organizational priority" for Optum and a "shared responsibility" between Optum and its clients. For Optum, "as a PBM – and I have said this multiple times before – our guiding principle is around doing what's best first and foremost for members, and secondly for our clients."

183. In practice, however, the PBM Respondents knowingly engage in, and incentivize, conduct that causes certain patients to bear the burden of artificially inflated drug prices.

184. The PBM Respondents are aware that commercial payers typically retain the rebates they receive, and do not pass them on directly at the point of sale to their member patients whose prescriptions generated the rebates. By retaining the rebates, the commercial payers may lower their own overall costs of covering health care benefits. This may in turn partially reduce the amount that employees have to contribute in premiums. But retaining the rebates also shifts the burden of expensive medications to chronically ill diabetics, who must pay out-of-pocket costs such as coinsurance and deductibles based on the inflated insulin list prices associated with higher rebates. As Caremark explained in internal presentations, this exploitative cost-shifting means "more members are exposed to the full cost of drugs via HDHPs and coinsurance plans" and that "[o]ut-of-pocket costs are significant for some members."

185. Typically, insurance spreads risk among the insured population, with those who do not make claims effectively subsidizing those who do. Thus, for health insurance, the healthy generally subsidize the sick or those who need medical treatment. But the strategies that have driven up list prices and rebates on insulin products, and shifted the brunt of that impact to list-

price-sensitive patients, result in the opposite dynamic: diabetics subsidizing the healthy. Indeed, a [redacted] Senior Manager criticized the payers' practice of retaining the entire rebate instead of sharing it with the patients whose prescription earned the rebate: "in the spirit of fairness, I don't see how it's justifiable to charge someone 100% of the cost of the drug (during the deductible), while you receive a rebate on the backend – even if you spread that across everyone's premiums. I can't think of any other insurance industry that works like that[.]"

186. Nonetheless, the PBM Respondents intentionally design and market formularies that enable and exacerbate this cost-shifting by excluding low WAC insulin drugs in favor of high WAC, highly rebated products. As the PBM Respondents well know, low WAC products benefit patients in deductible and coinsurance plans by helping these patients pay less out of pocket at the point of sale. A Caremark financial model vividly illustrates this point with a "cost ranking" of the options for the plan and for the member:

[redacted]

187. As this model demonstrates, excluding a low WAC drug in favor of the high WAC version is the worst option for member patients, but, according to Caremark, potentially a "huge windfall for the payer." Indeed, in the deductible phase, when the member shoulders the full list price of the drug, the payer functionally makes money off the patient's prescription because it pays nothing but collects large rebates.

188. The PBM Respondents widely recognize this phenomenon. In 2020, Caremark calculated that a patient in the deductible phase pays $[redacted] for a monthly prescription of high WAC Novolog pens—equal to [redacted]% of the net cost—while the payer pays nothing and collects $[redacted] in rebates. Even after meeting the deductible, a patient with 20% coinsurance still pays $[redacted]—the entire net cost for Novolog—out-of-pocket. The payer—who is supposed to share in drug costs—collects a rebate equal to the remaining 80% of the list price and ends up with a net cost of $0 for the Novolog prescription. In June 2019, ESI calculated that 33% of patients in HDHPs paid $[redacted] or more for a 30-day supply of insulin, and 13% of patients paid $[redacted] or more.

189. When Novo introduced an insulin affordability program that threatened to disrupt this established dynamic, Caremark expressed concerns. Though the program was designed to make insulin more affordable for many diabetics, Caremark feared it could incentivize patients to

purchase insulin outside of their insurance benefit, resulting in a "loss of value" to Caremark's payer clients, who would "miss a rebate on a claim they paid little for in [the] first place."

190. Optum's financial models show a similar troubling dynamic with Lantus. A [redacted] model created for Optum's Formulary Management Committee identifies a $462 list price for high WAC Lantus vials—[redacted] According to the model, the payer collects a $[redacted] rebate per prescription, transferring the burden of the high list price to patients with deductibles and coinsurance.

191. Not only do the PBM Respondents knowingly design formularies that can shift costs on to patients by preferring high WAC, highly rebated drugs, they also incentivize and encourage commercial payers to select these types of formularies. In 2019, Optum strategized about new formulary options for low WAC versions of drugs and modeled the "client and member financial impact" for "coinsurance versus flat copay." Though the "[low WAC] is [redacted] after rebate and Preferred Status," Optum noted that "clients with coinsurance benefits will see member cost decrease and client cost increase if the client covers [low WAC versions]." Optum posited that for clients on their flagship Premium formulary and with a coinsurance or deductible benefit design, blocking the low WAC versions was "the best financial option." It was also Optum's "default option."

192. The PBM Respondents provide modeling and consulting services to their clients showing how commercial payers can benefit from "rebate maximizing strategies," thereby incentivizing payers to adopt the exploitative cost-shifting strategies. For example, in a 2021 [redacted] outlined that the objectives of its custom client formulary consulting team include assisting with "[r]ebate modeling" to "upsell … rebate opportunities" and "[e]ncourage clients to adopt more aggressive formulary management strategies." To lure a health plan client away from [redacted], [redacted] aimed "to demonstrate to [redacted] (including their CEO) that [it] could develop a formulary for [redacted] that drives rebates at the expense of lowest net cost." In other words, [redacted] wanted to show [redacted] that it could increase total rebates, even if it also meant increasing the overall net spend.

193. The PBM Respondents could mitigate the detrimental effects of exploitative cost-shifting by requiring that rebates be shared with member patients at the point of sale, but instead use their gatekeeper role to incentivize a mode of competition that is detrimental for patients while highly lucrative for themselves. The PBM Respondents are aware that point-of-sale rebates would reduce or eliminate exploitative cost-shifting, and offer voluntary point-of-sale rebate programs that specifically "target[] … the plans with high deductible or co-insurance"—i.e., those benefit designs that most impact patients whose out-of-pocket expenditures are based on list prices. For example, the member's out-of-pocket cost for the hypothetical prescription in paragraph 186 would decline from $[redacted] to $[redacted] with point-of-sale rebates.

194. Point-of-sale rebates, however, lower patient out-of-pocket costs at the expense of the payer. As reflected in paragraph 186, point-of-sale rebates is the "[h]ighest cost" option for the payer.

195. The PBM Respondents do not require their clients to use point-of-sale rebates—in fact, the PBM Respondents' chase-the-rebate strategy disincentivizes payers from adopting them. Further, the PBM Respondents usually withhold specific drug-level rebate and net cost information that could allow payers to understand exactly how the cost-shifting is affecting their patients.

196. Consequently, payers have failed to widely adopt point-of-sale rebating practices. Optum reported "limited uptake of point of sale rebates." Caremark observed that a "majority" of its clients "opt to keep rebates at the plan level." And ESI found that "very few clients" have chosen to implement point-of-sale rebates.

197. Industry studies confirm that commercial payers tend not to pass on rebates at the point of sale and instead retain most of the rebate value. Although these rebates may reduce the plan's overall cost of providing health care benefits, they may have little impact on the patient's premium. For example, according to the 2023 Milliman Medical Index, employers allocate 70% of rebates to reduce the corporate employers' own contributions to premiums, while only dedicating 30% to reducing employees' (patients') premiums. This study observed that none of the rebates were directed towards reducing patients' out-of-pocket drug cost`s.

198. Payers have expressed concerns about the PBM Respondents' lack of transparency about drugs' true net cost, and some have specifically identified the impact on patients with high deductibles or coinsurance as a source of their concern. A 2020 internal Caremark presentation succinctly noted that according to clients and consultants, "Rebates are a black box."

199. The PBM Respondents have typically been dismissive of payers' requests for more information on rebates or the actual net costs for drugs. The PBM Respondents even rebuffed specific inquiries about lower list price options such as the low WAC insulins. For example, in 2021, [redacted] received "quite a few questions" from a large consultant asking whether the exclusion of low WAC Humalog still made sense after a recent list price cut. [redacted] internally told employees that it was "pencils down" and "less about explaining the 'math'"; instead, "the ball is in the court of the payers" to switch to [redacted] formulary, which included lower list priced products such as low WAC Humalog. [redacted] informed the consultant that [redacted] was an option for clients willing to "miss[] out on the rebate," falsely stating "these lower list price drugs like [low WAC Humalog] do not have rebates on them."

200. High out-of-pocket patient costs that result from exploitative cost-shifting can lead to lower drug adherence, higher medical costs, and adverse health outcomes. The PBM Respondents know these impacts are particularly felt with insulin. In a 2019 press release, ESI acknowledged that "1 in 4 people with diabetes who use insulin admitted to cutting back on the use of insulin because of cost." In 2023, ESI's President admitted, "[w]e do know that a lot of patients, unfortunately, don't take their drugs as prescribed because of cost concerns." Similarly, Caremark's website explains "when people can afford their medications, they are more likely to take them." Optum's website recognizes the "proven link between rising member cost share and lower medication adherence," and a UnitedHealth press release states that better adherence

"contribut[es] to better health and reduc[es] total health care costs for clients and the health system overall."

201. By denying clients access to drug net cost information, the Respondents prevent commercial payers from fully appreciating how plan designs that base patient cost-sharing on list price, such as coinsurance and deductibles, can cause this exploitative cost-shifting and harmful health effects. Payers may not realize that their patients pay out-of-pocket amounts that can exceed the entire net cost of highly rebated drugs. Respondents' lack of transparency accompanying their chase-the-rebate strategy precludes the payers' ability to make fully informed decisions and better protect their patients. This lack of transparency allows Respondents to avoid competing directly to win over clients based on the lowest net cost.

H. Even after regulatory changes forced manufacturers to lower some insulin list prices, Respondents sought to preserve the high rebates attributable to high list price insulin products

202. Despite the growing recognition of the harm to certain patients from high insulin list prices, manufacturers maintained the artificially inflated list prices of their high WAC insulins until a regulatory change forced price cuts.

203. The American Rescue Plan of 2021 repealed the Average Manufacturer Price (AMP) Cap. Under Medicaid regulations, manufacturers must pay Medicaid rebates equal to the difference between the current average price of the drug paid by retail pharmacies and wholesalers and the inflation-adjusted list price of the drug (sometimes referred to as the Medicaid inflation penalty). If a drug's list price has increased faster than inflation, the manufacturer has to rebate the difference to Medicaid. The AMP Cap, in place since 2010, had capped the Medicaid rebate at 100% of the drug's average price, even if manufacturers continued to raise list prices. The repeal of the AMP Cap, however, took away this 100% rebate maximum. Thus, beginning in 2024, insulin manufacturers who had dramatically increased list prices (exceeding the inflation rate) would be required to pay a Medicaid rebate in excess of 100% of the drug's price on every unit dispensed in Medicaid.

204. Humalog, Novolog, and Lantus, which had experienced up to sevenfold list price increases, were among the "high risk" products. The insulin manufacturers projected incurring hundreds of millions of dollars in Medicaid liability due to the AMP Cap repeal. Because of the relationship between the AMP Cap and list price, however, manufacturers could mitigate the effect of the AMP Cap repeal by lowering list price.

205. On March 1, 2023, Lilly announced that it would reduce the list price of high WAC Humalog by 70%, as well as set the price of its low WAC Humalog at $25 a vial.

206. On March 14, 2023, Novo announced that it would reduce the list price of high WAC Novolog by 75% and Levemir by 65%. Since Novo cut the list price of high WAC Novolog down to the list price of low WAC Novolog, there is no longer a low WAC/high WAC Novolog distinction.

207. On March 16, 2023, Sanofi announced that it would reduce the list price of high WAC Lantus by 78% and Apidra by 70%. Because the list price of high WAC Lantus was now lower than low WAC Lantus, Sanofi discontinued low WAC Lantus.

208. The Respondents were concerned, as a Vice President at [redacted] described, that these insulin list price cuts would "have a dramatic impact" in the commercial space, because a lower list price product "isn't changing the net, but it would change how you get to that net." In other words, a list price reduction on insulin would also reduce WAC-based rebates and WAC-based fees, as well as the PBM Respondents' and GPO Respondents' profits. The Vice President at [redacted] further explained that list price reductions were a risk to [redacted] because they could "impact rebate guarantees" and a risk to payers if they "rely[] on a certain level of rebates."

209. Optum projected that the WAC decreases on Lilly's rapid-acting insulin products would cost Optum $[redacted] in profits and $[redacted] in rebate dollars—[redacted]% of its total rebates. Optum further expected to lose another [redacted]% of rebates from anticipated list price cuts to long-acting insulins.

210. However, the PBM Respondents were determined not to give up on their high list price, high rebate strategy after the AMP Cap repeal. They realized switching to newer insulin products, which would not be affected by the AMP Cap repeal, [redacted]. For example, in May 2022, Lilly gave a presentation to Optum [redacted]. As a relatively new product that had not undergone dramatic price increases over time, the Humalog U-200 pen was not impacted by the AMP Cap repeal and thus not subject to list price cuts. Before the AMP Cap repeal, the Humalog U-100 and Humalog U-200 pens [redacted]. After Lilly cut the list price of Humalog U-100 from $530.40 to $159.12, it would generate only a $[redacted] rebate per prescription. However, the list price of Humalog U-200 would not change, leaving its $[redacted] rebate per prescription intact.

211. Caremark and ESI considered updating their flagship formularies to preference newer insulins, which had not experienced dramatic list price increases and were therefore unaffected by the AMP Cap repeal. [redacted] discussed replacing [redacted] with [redacted], a newer [redacted] insulin, in the rapid-acting category to "avoid the disruption … on the rebate." In the long-acting category, [redacted] also considered preferring high WAC [redacted], similarly not impacted by the AMP Cap repeal. [redacted] discussed replacing [redacted] with [redacted] or with a new [redacted] biosimilar entrant, which as a "brand new drug" would be priced de novo.

212. In addition, in reaction to "drug manufacturers adjusting prices in response to public policy changes and … the launch of several Humira biosimilars," Caremark created a new "Choice" Formulary for 2024 that specifically favors higher WAC products with higher rebates. Caremark explains that clients "can achieve low net cost with lower list price strategies when appropriate and applicable, or rebated product strategies with our new Choice formularies."

213. Despite the recent list price cuts on some insulin products, the Respondents are determined to continue chasing the high price, highly rebated products for their commercial formularies and their own profit.

VI. RESPONDENTS' CONDUCT RESULTED IN HARM TO CONSUMERS AND COMPETITION

214. Although the Respondents claim to prioritize patient well-being, their actions reveal a pattern of anticompetitive and unfair conduct. Respondents' practices, whether viewed individually or collectively, inflict serious harm on patients whose drug costs are calculated based on the inflated, unrebated list price and potentially on patients more broadly.

215. The Respondents' chase-the-rebate strategy has flipped healthy price competition on its head. Respondents favor high list price, highly rebated drugs over low list price alternatives at a similar net price because the PBMs and GPOs retain more rebates and fees from the higher list price drugs. The Respondents use their size, scale, and position in the prescription drug transaction chain to pressure manufacturers to secure favorable formulary placement by prioritizing the size of the rebates. Respondents push manufacturers to achieve a lower net price *with the highest rebates and fees*. As one of Viatris's head PBM negotiators testified, what matters to the PBMs and their clients is "ultimately *how* they get to the net price" (emphasis added) via "smaller rebates or larger rebates." All else equal, many prefer getting to the net cost through larger rebates.

216. The PBM Respondents' decision to prioritize highly rebated drugs on exclusionary formularies has incentivized insulin manufacturers to raise their list prices well over the rate of inflation to counteract the ever-increasing rebates and fees. A 2020 USC Schaeffer Center study found that for prescription drugs sold from 2016 to 2018, a $1 increase in rebates, on average, was associated with a $1.17 increase in WAC.

217. These artificially inflated list prices create more rebates and fees for Respondents and their clients, but do little to reduce a drug's net cost. From 2012—when Caremark introduced the first exclusionary formulary—to 2017, manufacturers more than doubled the list prices of their primary insulin drugs (Lantus, Novolog, and Humalog). Absent the PBM Respondents' chase-the-rebate strategy, the net prices of insulin products, after rebates, may have been lower.

218. The Respondents' conduct deterred insulin manufacturers from competing by lowering their list prices. Efforts to lower list prices was met with resistance by the Respondents. When manufacturers launched low WAC, low rebate versions of their insulins, the PBM Respondents systematically disadvantaged these products on formularies. Because of Respondents' conduct, many diabetics have been denied access to more affordable lower list price insulin products.

219. In response to PBM Respondents' decisions, manufacturers introduced new insulin products with a high price and a high rebate to secure placement on the PBM Respondents' flagship formularies. For instance, when Viatris launched Semglee, the first insulin biosimilar, with a lower list price than competing drugs, the PBM Respondents excluded it from

their flagship formularies. Viatris secured formulary access for Semglee only after it relaunched the product with a high list price and high rebate. Similarly, Lilly launched Lyumjev with a high list price and a rebate [redacted], because "counterintuitive[ly]," Lilly recognized that "[l]aunching at a list price discount to Humalog may present a barrier to formulary adoption."

220. On the other side of the industry, the PBM Respondents' chase-the-rebate strategy and formulary decisions also encourage commercial payers to prioritize rebates and select formularies that exclude low list price drugs. The Respondents have leveraged the murkiness of prescription drug pricing to their own advantage, by intentionally obscuring drug-level information on rebates and net costs, requiring clients to use the total guaranteed rebate value as a primary financial metric for clients selecting a PBM. The PBM Respondents' focus on enlarging and promoting aggregate rebates helps keep payers "addicted to rebates."

221. The PBM Respondents cause further harm by encouraging and incentivizing plan designs where patients' contributions are based on these inflated list prices, including coinsurance based on the unrebated price and deductibles that require payment of the full list price. As a result, a patient may end up paying more than the drug's entire net cost to the payer. This unfair and exploitative cost-shifting leads to "a windfall" for payers—at the expense of the patient who pays out of pocket based on the inflated list price. But because PBMs control the information on drug-level net costs, commercial payers—particularly smaller or less sophisticated employers—may not even realize the extent that cost-shifting is occurring.

222. Respondents' conduct causes substantial injury to insulin patients whose out-of-pocket costs are based on artificially inflated list price. This injury is not limited to the direct increase in out-of-pocket costs for their medication at the pharmacy counter. When patients cannot afford their insulin, they may skip necessary doses or stop taking the medication altogether. Patients who do not take necessary insulin face a greater risk of hospitalization and of additional medical complications, all of which can substantially increase costs for the patient and the commercial payer. It can also lead to short-term or long-term serious adverse health effects for patients, including death.

223. Patients have little ability to avoid the substantial injury incurred as a result of the PBM Respondents' anticompetitive and unfair practices. Switching plans would be ineffective as many plans are similarly affected by high list prices and high drug costs. Even if it were effective, patients cannot easily switch formularies, because the PBMs and GPOs do not contract directly with patients. Rather, patients must go through an insurer—often their employer—to benefit from the rates negotiated by the PBMs and GPOs. In at least one instance, Optum received a patient complaint from someone who had been switched from ESI to Optum but who "did not choose Optum."

224. The Respondents' actions interfere with the free exercise of consumer decision-making and hinder marketplace self-correction with respect to the exclusion of low WAC insulin products and cost-shifting of high WAC, highly rebated insulin products onto list-price-sensitive patients. Even if patients could effectively switch plans or formularies, the PBM Respondents have made the process so opaque that patients would be operating blindly. Many patients do not know what formulary undergirds their insurance options, so they cannot comparison-shop when

making decisions about their insurance coverage. Moreover, patients often do not realize the extent to which cost-shifting is occurring. Patients generally have no knowledge of the rebates and fees received by the PBM Respondents and payers; payers rarely disclose their existence in plan documents and almost never disclose the rebate and fee amounts.

225. Additionally, many plan documents are confusing, unclear, or elusive about the extent of the patient cost-sharing obligations. Thus, patients in deductible and coinsurance plans may be unaware that their "share" of the drug cost far exceeds the amount implied by their plan documents and may in fact exceed the payer's entire net cost.

226. The substantial injury to consumers is not outweighed by any countervailing benefits to consumers or to competition. The PBM Respondents' systematic practice of excluding a low WAC drug in favor of an identical high WAC alternative from the same manufacturer does not lower net prices for the high WAC drug. While some rebates may serve to lower premiums across patients in a health plan, not all rebates are used to lower patient premiums. Some rebates are retained by the PBMs and GPOs, and the majority of the remaining rebates are retained by the commercial payer. For insulin patients forced to pay coinsurance and deductible payments based on the list price, dramatically higher out-of-pocket costs for insulin are significantly more harmful than the possibility of slightly lower premiums.

227. Further, the increased risk of hospitalization and additional medical complications for patients who skip necessary insulin dosages result in higher expected costs for patients as well as commercial payers. The costs of hospitalization and further adverse health conditions are significantly greater than the cost of regularly taking insulin, and outweigh any potential small decrease in employee health premiums attributable to any rebates shared with the commercial payer.

228. The hodge-podge of affordability programs offered by PBM Respondents do not provide an adequate solution for insulin patients. Since the focus on PBM practices by Congress and other entities, the PBM Respondents have each begun offering voluntary programs designed to cap patient out-of-pocket costs, but the program designs impose costs on payers, which, in the words of [redacted], "[c]lients don't like." As a result, few commercial payers have adopted these programs, and their benefits are largely illusory. To illustrate, ESI's "Patient Assurance Program" and Optum's "Critical Drug Affordability" program both purport to cap a patient's out-of-pocket costs—at $25 and $35, respectively—but each program conditions participation on the plan capping a patient's copay and compensating for the cost. Caremark's "RxZero" program purports to lower a patient's out-of-pocket costs to nothing, except it requires plans to absorb the patient's cost of drugs in the program.

229. In 2023, Optum found that of the five drug categories in its Critical Drug Affordability offering, insulin accounted for [redacted] of the claims with greater than [redacted] patient out-of-pocket costs. In its 2023 Employer Health Benefits annual survey, KFF (f/k/a Kaiser Family Foundation) estimated that, despite these programs, only 45% of all workers with employer-sponsored health insurance had reduced or no cost-sharing for chronic condition maintenance drugs, such as insulin for diabetes.

230. Other PBM programs that claim to benefit patients are similarly illusory, as the PBM Respondents are focused on retaining payer clients. For instance, the PBM Respondents claim to encourage payers to provide point-of-sale rebates to their patients but make doing so unattractive to payers, including by sometimes charging additional fees and by obscuring the details of the cost-shifting onto list-price-sensitive patients for highly rebated products. And PBM Respondents know that a voluntary point-of-sale rebate program is unlikely to be adopted by the payer because point-of-sale rebates reduce the rebates kept by the payer.

231. There are no valid justifications for the Respondents' prioritizing of rebates over lower net prices when negotiating to secure preferred formulary placement. Offering a product with a substantially similar net price but with much higher fees and higher out-of-pocket costs to patients is not offering a better product. The chase-the-rebate strategy has resulted in reduced options for patients who can more readily afford the low WAC options that are excluded from their formularies and incentivizes manufacturers to raise list prices.

232. Although PBM Respondents and GPO Respondents collect more money from higher list price products, they do so simply because the rebates and fees are based on a percentage of list price—not because higher list price products can be administered more efficiently than lower list price products. The PBM Respondents and GPO Respondents provide no additional services to justify the higher payout on higher list price drugs from the assortment of WAC-based fees the PBM Respondents and GPO Respondents extract from manufacturers. As an Optum executive wrote, the "% basis is key" for these fees, rather than a flat fee. Similarly, ESI's Vice President of Pharma Contracting and Strategy had no justification for keeping the [redacted] fee as a percentage of WAC other than "that's how it's always been."

233. There is no justification for the PBM Respondents' using rebate value instead of net prices to attract clients. Despite the illusion of choice between different formulary options, the use of rebate value as a financial metric, coupled with the payers' incomplete information on cost, drives payers to each PBM Respondent's respective high WAC, high rebate flagship formulary. Nor does the additional rebate value on a high WAC product over a low WAC alternative with a substantially similar net price result in more efficient drug usage. For instance, when a formulary prefers high WAC Humalog over low WAC Humalog, the patient receives the exact same life-saving medication, just at a higher price.

VII. RESPONDENTS' CONDUCT IS ONGOING OR LIKELY TO RECUR

A. The list prices of some insulin products remain artificially high

234. Despite recent list price decreases on some insulin products, the list prices of other insulin products remain high. In particular, newer insulins have entered the market at, and will likely remain at, artificially inflated prices due to the Respondents' chase-the-rebate strategy.

235. Several insulin products in the long-acting category remain at artificially high prices. When Lilly launched its long-acting insulin Basaglar in 2017, Lilly specifically priced it at a "modest discount" off the list price of Sanofi's Lantus, which itself had been artificially

inflated from many years of price increases and high rebates. Lilly determined that a 10-15% discount off the Lantus price "str[uck] the optimal … balance between … meeting market expectations for list price with a modest cost reduction for some patients exposed to rising out of pocket costs" and gaining formulary access. Lilly decided against a greater discount, because "[a]t a significantly lower list price relative to Lantus, Basaglar's formulary access will likely be reduced due to PBM / Plans preference for rebate stream."

236. Despite Lantus's subsequent list price decrease, Lilly continues to sell Basaglar at an artificially inflated price.

237. When Sanofi launched its long-acting insulin Toujeo in 2015, Sanofi specifically set the list price at parity on a per unit basis with Lantus, which had an artificially inflated list price from many years of price increases and high rebates. Despite Lantus's subsequent list price decrease, Sanofi continues to sell Toujeo at an artificially inflated price.

238. When Novo launched its long-acting insulin Tresiba in 2016, Novo set the list price at a 10% premium on a per unit basis over the list price of its other long-acting insulin product, Levemir, which had been artificially inflated from many years of price increases and high rebates. Despite Levemir's subsequent list price decrease, Novo continues to sell high WAC Tresiba at an artificially inflated list price.

239. The same dynamic has occurred in the rapid-acting insulin class. When Novo launched its rapid-acting insulin Fiasp in 2017, Novo set Fiasp's list price at parity with its other rapid-acting insulin product, Novolog, which had an artificially inflated list price from many years of price increases and high rebates. Despite Novolog's subsequent list price decrease, Novo continues to sell Fiasp at an artificially inflated list price.

240. When Lilly launched its Humalog U-200 pen in 2015, Lilly set the list price at parity on a per unit basis with Humalog U-100, which had an artificially inflated list price from many years of price increases and high rebates. Despite Humalog U-100's subsequent list price decrease, Lilly continues to sell Humalog U-200 at an artificially inflated list price.

241. When Lilly launched its rapid-acting insulin Lyumjev in 2020, Lilly set the list price at parity with its other rapid-acting insulin product, Humalog, which had an artificially inflated list price from many years of price increases and high rebates. Despite Humalog U-100's subsequent list price decrease, Lilly continues to sell Lyumjev at an artificially inflated list price.

242. While the repeal of the AMP Cap thwarted the manufacturers' price inflation and by extension the Respondents' chase-the-rebate strategy on some older insulin products, current and future insulin biosimilar entrants are not affected by the repeal and can launch with high list prices and high rebates, which Novo characterized as posing "a serious threat" to its ability to compete for formulary coverage. Due to how insulin products vie for favorable formulary coverage, Novo predicted that new biosimilars staying at a high WAC was the "likely scenario." And Viatris continues to offer a higher WAC version of Semglee, which was not affected by the AMP Cap repeal.

243. The artificially inflated insulin list prices, with higher rebates and higher WAC-based fees, continue to benefit PBM Respondents and GPO Respondents, at the expense of list-price-sensitive diabetics.

B. The PBM Respondents continue to exclude low WAC insulin products in favor of their high WAC, highly rebated counterparts

244. The PBM Respondents continue to prefer some high list price insulin products that generate high rebates and fees on their flagship formularies, while excluding low WAC alternatives.

245. Caremark's 2024 flagship Standard Control Formulary prefers high WAC Tresiba and excludes low WAC Tresiba. Caremark's newly created 2024 Advanced Control Choice Formulary specifically focuses on high rebate products. It prefers high WAC Tresiba and excludes low WAC Tresiba, and prefers Fiasp and excludes the now lower-priced Novolog.

246. ESI's 2024 flagship National Preferred Formulary prefers high WAC Tresiba and high WAC Semglee, excluding the low WAC version of each product.

247. Optum's 2023 flagship Premium Formulary preferred high WAC versions of Humalog and Lantus and excluded their respective low WAC versions. While under regulatory scrutiny from the FTC's investigation, Optum changed its Premium Formulary such that its 2024 formulary now covers the low WAC versions of insulin products on the same formulary tier as the respective high WAC versions.

248. The PBM Respondents have changed their formularies at least every year, sometimes in the middle of the year, and all three PBM Respondents have the opportunity and the incentive to prefer high WAC insulins over their low WAC alternatives in the future.

C. The PBM Respondents exclude low WAC versions of other drugs from formularies

249. In addition to insulin, the PBM Respondents exclude or disadvantage low WAC versions of other drugs in favor of the high WAC versions. For example, in January 2019, Gilead Science (through a subsidiary) launched low WAC versions of its Hepatitis C medications Harvoni and Epclusa at significant discounts to the high WAC versions. Although brand companies sometimes offer low WAC versions of their drugs in response to competition from generic drugs, Gilead launched these low WAC versions unprompted by that prospect: Harvoni and Epclusa were years away from the threat of generic entry. The PBM Respondents all preferred the high WAC versions of both drugs on their 2024 flagship formularies and excluded the low WAC alternatives.

250. The PBMs' practice of excluding the low WAC products in favor of high WAC versions is likely to continue for new products. For example, in January 2023, Amgen simultaneously launched high WAC and low WAC versions of Amjevita, pricing the two drugs respectively at 5% and 55% off Humira's list price. In July 2023, Boehringer Ingelheim launched high WAC Cyltezo and, in October 2023, a low WAC version, pricing them respectively at 5% and 81% off Humira's list price. In January 2024, Optum preferred the high WAC versions of

Cyltezo and Amjevita and excluded their low WAC alternatives, and ESI preferred the high WAC version of Cyltezo and excluded the low WAC alternative, on their flagship formularies.

251. The PBM Respondents retain the same incentives and opportunities to use low WAC formulary exclusion practices with future products. The PBM Respondents' continued use of this strategy is likely to cause substantial injury to consumers whose out-of-pocket costs are based on the list prices of drugs.

D. The PBM Respondents have the opportunity and incentive to continue causing the exploitative cost-shifting onto certain consumers

252. The PBM Respondents and GPO Respondents benefit from the high rebates and high fees associated with the high list prices of pharmaceutical products. The PBM Respondents are likely to continue preferring high price, highly rebated products on their flagship formularies, and incentivizing commercial payers to shift the cost of high list price drugs onto certain patients.

253. The list prices—and rebates—associated with product categories beyond just insulin have dramatically increased in recent years. For example, Amgen increased the list price of Enbrel, a high list price and highly rebated drug used to treat inflammatory conditions, 457% between 2002 and 2020. Additionally, the list price of Lilly's immunomodulator Taltz, a high list price and highly rebated monoclonal antibody, increased 52.9% from 2016 to 2022.

254. The PBM Respondents' systematic preferencing of high price, highly rebated products incentivizes drug manufactures to compete using high list prices and high rebates and fees. It also leads to commercial payers adopting formularies preferring products with high list prices and high rebates and fees, while engaging in exploitative cost-shifting that forces list-price-sensitive patients to bear the burden of artificially inflated list prices. Respondents' continued conduct with respect to exploitative cost-shifting is likely to cause substantial injury to consumers whose out-of-pocket costs are based on the list prices of drugs.

VIII. VIOLATIONS OF THE FTC ACT

COUNT I – Unfairly Competing by Rebate Preferencing

255. The allegations of paragraphs 1-254 above are incorporated by reference as though fully set forth herein.

256. The Respondents systematically prefer high list price insulin products, with high rebates and fees, over similar low list price products, with low rebates and fees, on formularies to inflate the perceived value of their commercial drug formularies and offer higher rebate guarantees. This systematic preferencing of products with a high rebate and fee value is a method of competition, not an inherent condition of the PBM or drug industry.

257. The Respondents' favoring of high list price insulin products, with high rebates and fees, while disadvantaging or excluding similar versions with a lower list price and lower rebates and fees and obscuring actual net cost, is unfair because it goes beyond competition on the merits.

258. The Respondents' conduct is coercive, exploitative, and restrictive because it (1) induces rival manufacturers to compete for formulary placement by prioritizing rebates over lower net prices; (2) exploits and abuses vulnerable patient populations by denying them access to more affordable medications; and (3) restricts commercial payers' access to information on aggregated rebate numbers rather than drugs' actual net cost.

259. The Respondents' conduct tends to negatively affect competitive conditions because (1) drug manufacturers are incentivized to compete for formulary placement by inflating list prices to counteract high rebates and fees and are deterred from lowering the artificially inflated list prices to compete with other products; (2) consumers are forced to purchase high list price products, and to pay higher out-of-pocket costs based on the artificially inflated list prices; and (3) price competition between Respondents is often limited to rebates, causing commercial payers to make decisions primarily based on the size of rebates and rebate guarantees.

260. There is no valid or cognizable justification for the Respondents' unfair method of competition.

261. The Respondents' conduct constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

COUNT II – Unfair Practice of Formulary Exclusion of Low WAC Insulin Products

262. The allegations of paragraphs 1-254 above are incorporated by reference as though fully set forth herein.

263. Through their development of commercial formularies, the PBM Respondents have a significant role in controlling consumers' affordable access to prescription medications. The PBM Respondents' systematic exclusion of low WAC insulin products from their most-utilized commercial formularies and custom client formularies, in favor of identical high WAC insulin products, is an unfair act or practice.

264. The PBM Respondents cause and are likely to continue to cause substantial injury to insulin consumers whose out-of-pocket costs are based on list prices. Respondents' practice limits consumers' choice, forcing them to purchase the high WAC versions of insulin products instead of the identical low WAC versions. As a result, some patients pay more for insulin than they would if the low WAC version were available on formulary. Higher prices also tend to lead to decreased adherence and adverse health outcomes for patients.

265. Insulin consumers cannot reasonably avoid the harm caused by the PBM Respondents' unfair formulary exclusion practices. Patients cannot choose to discontinue purchasing insulin and cannot reasonably switch insulin products or health plans to avoid the harm.

266. The harm to insulin consumers whose out-of-pocket costs are based on list prices is not outweighed by countervailing benefits to consumers or competition.

267. The PBM Respondents' systematic exclusion of low WAC insulin products from their most utilized commercial formularies and custom formularies constitutes an unfair act or practice in violation of Section 5(a), (n) of the FTC Act, 15 U.S.C. § 45(a), (n).

COUNT III – Unfair Practice of Exploitative Cost-Shifting

268. The allegations of paragraphs 1-254 above are incorporated by reference as though fully set forth herein.

269. The PBM Respondents unfairly create and implement the system of manufacturer rebates, construct exclusionary formularies that preference high-list priced and highly rebated insulin products, and assist in other aspects of plan design—the combined effect of which shifts the cost of high insulin prices of drugs onto certain insulin patients.

270. The PBM Respondents are aware that their rebate and formulary practices result in those patients whose out-of-pockets costs are based on the unrebated list price—rather than the significantly lower, rebated net price—paying more out-of-pocket for their insulin drugs, sometimes even more than the entire net cost of the drug.

271. The PBM Respondents' exploitative cost-shifting practices cause and are likely to continue to cause substantial injury to consumers by increasing the price of insulin products to certain patients. Higher insulin prices can also lead to decreased adherence and adverse health outcomes for patients.

272. Insulin consumers cannot reasonably avoid the harm caused by the PBM Respondents' unfair cost-shifting practices. Patients cannot choose to discontinue purchasing insulin, cannot easily switch insulin products or health plans, cannot access confidential rebates to compare the cost-sharing provisions between health plans, and cannot negotiate plans' cost-sharing terms.

273. The harm to insulin consumers whose out-of-pocket costs are based on drugs' list prices is not outweighed by countervailing benefits to consumers or competition.

274. The PBM Respondents' involvement in cost-shifting of the high insulin list prices of drugs onto certain patients constitutes an unfair act or practice in violation of Section 5(a), (n) of the FTC Act, 15 U.S.C. § 45(a), (n).

NOTICE

Notice is hereby given to the Respondents that the twenty-seventh day of August, 2025, at 10:00 a.m., is hereby fixed as the time, and the Federal Trade Commission offices at 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580, as the place, when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted. If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time provided above shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the Respondents file their answers. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the pre-hearing scheduling conference (but in any event no later than five (5) days after the last answering Respondent files its answer). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving a Respondent's answer, to make certain initial disclosures without awaiting a discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Respondents' conduct violates Section 5 of the Federal Trade Commission Act, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. Prohibit Respondents from excluding or disadvantaging low WAC versions of high WAC drugs made by the same manufacturers whenever the Respondent covers the high WAC drug on a formulary.

2. Prohibit Respondents from accepting compensation based on a drug's list price or a related benchmark.

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3. Prohibit Respondents from designing—or assisting with designing—a benefit plan that bases patients' deductibles or coinsurance on the list price, rather than the net cost after rebates.

4. Order any other relief appropriate to correct or remedy the Respondents' violations.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this twentieth day of September, 2024.

By the Commission, Commissioner Holyoak and Commissioner Ferguson recused.

SEAL:

April J. Tabor
Secretary

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CERTIFICATE OF SERVICE

I hereby certify that on November 26, 2024, I caused the foregoing document to be filed electronically using the FTC's E-Filing System, which will send notification of such filing to:

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Clerk of the Court

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Administrative Law Judge

I also certify that I caused the foregoing document to be served via email to:

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